EQUIPMENT AUTOMATION PHASES
RELEASE 11.01.00
FUNCTIONAL REQUIREMENT SPECIFICATION

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FT PharmaSuite® 11.01.00 - Functional Requirement Specification Equipment Automation Phases

Contents

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1 Introduction

This document details the requirements of the functions implemented by the phases specific to equipment automation integration. The phases are executed in the Production Execution Client of PharmaSuite.

Each requirement is composed of a name (e.g., Preview mode) and a unique identifier (e.g., GID-1234567) and is extended with its business attributes (GxP Relevance, Business Impact) and its compliance attribute (21 CFR Part 11 Relevance).

For requirements with **Framework capability** as identifier, see "Functional Requirement Specification Execution Framework" for their unique identifier [A1] (GID-2667986)).

The revision history lists the changes made to the document with the previous FactoryTalk PharmaSuite release as the comparison baseline. It provides individual tables for "Updated", "Added", and "Deleted" requirements that juxtapose the previous approved version with the new approved version of an item.

Bold typeface	Designates user interface texts, such as ▪ window and dialog titles ▪ menu functions ▪ panel, tab, and button names ▪ box labels ▪ object properties and their values (e.g., status).
Monospaced typeface	Designates code examples.

FT PharmaSuite® 11.01.00 - Functional Requirement Specification Equipment Automation Phases

2 Get OPC Values Phase (SR0341+)

The **Get OPC values** phase allows to read up to 50 tag values of one equipment entity from the automation layer. It supports the following data types:

- BigDecimal Value (Double, Float, Integer),
- Boolean Value: choice between Yes and No (true and false), and
- String Value.

An example use case is:

- Verify parameters of a mixer
  With one button tap, an operator can retrieve the values of all relevant set points of a mixer from the automation layer to check them against defined limits. Any violation can be tracked as an exception. Finally, the mixer speed is passed on to a subsequent phase for calculation or decision purposes.

    - Mixer speed should range between 400 rpm and 1000 rpm.
    - HeatingControl should be set to Yes.
    - HeatingTargetTemp should be 55 °C.
    - HeatingProfile should be 7.
    - HMI_InstructionText1 should be "Control visual foam situation".

Different phase modes enable the usage in various situations that can occur during processing:

- In the **Manual completion** mode, the operator manually triggers reading the values.
- In the **Automatic completion** mode, the phase reads the values and is completed automatically without any operator interaction.

The affected equipment entity, the affected properties, their values, and their timestamps are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2669415).

Anomalies that occur during processing are covered by the phase exception handling (GID-2669428) (e.g. equipment entity is not available).

After completion the phase displays the affected properties and their values in the Execution Window.

The Navigator displays the identifier of the affected equipment entity.

Figure 1: Get OPC values during execution

2.1 Layout

The phase provides individual layouts for its representation during execution (GID-2669413), in the Navigator (GID-2669414), and in the sub-report (GID-2669415).

2.1.1 Representation during Execution (SR0341.1+)

The representation during execution depends on the phase mode.

2.1.1.1 GID-2671213 PREVIEW MODE (SR0341.1.1)

1. \<Instruction text\>
   (taken from **Instruction (SR0341.8.1)** process parameter (GID-2671229))

2. Entity:

3. List of up to 50 property types in the order of the property-specific process parameters:

   - **Boolean Property Bundle:**
     List of boolean properties
     (taken from **Boolean property - Master (bundle identifier) (SR0341.8.12)** process parameter (GID-2671234))

   - **Numeric Property Bundle:**
     List of numeric properties
     (taken from **Numeric property - Master (bundle identifier) (SR0341.8.5)** process parameter (GID-2671239)

   - **String Property Bundle:**
     List of string properties
     (taken from **String property - Master (bundle identifier) (SR0341.8.9)** process parameter (GID-2671245))

4. **Get** button (disabled).

5. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

2.1.1.2 GID-2671214 ACTIVE MODE (SR0341.1.2)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0341.8.1)** process parameter (GID-2671229))

3. Entity: <equipment entity identifier> / <equipment entity short description>
   (taken from **Identified equipment entity (SR0341.8.2)** process parameter (GID-2671230))

4. List of up to 50 property types in the order of the property-specific process parameters:

   - **Boolean Property Bundle**:
     List of boolean properties
     (taken from **Boolean property - Master (bundle identifier) (SR0341.8.12)** process parameter (GID-2671234))

     - For the representation of the value, see **Get values (SR0341.2.3)** function (GID-2671223).

     - Last change timestamp per tag from automation layer or **Manual** in case a value has been overridden by using the **Override recorded value (SR0341.3.1.3)** user-triggered exception (GID-2671802).

   - **Numeric Property Bundle**:
     List of numeric properties
     (taken from **Numeric property - Master (bundle identifier) (SR0341.8.5)** process parameter (GID-2671239))

     - For the representation of the value, see **Get values (SR0341.2.3)** function (GID-2671223)

     - Last change timestamp per tag from automation layer or **Manual** in case a value has been overridden by using the **Override recorded value (SR0341.3.1.1)** user-triggered exception (GID-2671804).

   - **String Property Bundle**:
     List of string properties
     (taken from **String property - Master (bundle identifier) (SR0341.8.9)** process parameter (GID-2671245))

     - For the representation of the value, see **Get values (SR0341.2.3)** function (GID-2671223).

     - Last change timestamp per tag from automation layer or **Manual** in case a value has been overridden by using the **Override recorded value (SR0341.3.1.2)** user-triggered exception (GID-2671806).

5. **Get** button.

6. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.1.1.3 GID-2671215 C OMPLETED MODE (SR0341.1.3)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0341.8.1)** process parameter (GID-2671229))

3. Entity: <equipment entity identifier> / <equipment entity short description>
   (taken from **Identified equipment entity (SR0341.8.2)** process parameter (GID-2671230)

4. List of up to 50 property types in the order of the property-specific process parameters:

   ▪ **Boolean Property Bundle**:
   List of boolean properties
   (taken from **Boolean property - Master (bundle identifier) (SR0341.8.12)** process
   parameter (GID-2671230))

      ▪ Last change timestamp per tag from automation layer or **Manual** in case a value has been
      overridden by using the **Override recorded value (SR0341.3.1.3)** user-triggered
      exception (GID-2671802).

   ▪ **Numeric Property Bundle**:
   List of numeric properties
   (taken from **Numeric property - Master (bundle identifier) (SR0341.8.5)** process
   parameter (GID-2671239))

      ▪ Last change timestamp per tag from automation layer or **Manual** in case a value has been
      overridden by using the **Override recorded value (SR0341.3.1.1)** user-triggered
      exception (GID-2671804).

   ▪ **String Property Bundle**:
   List of string properties
   (taken from **String property - Master (bundle identifier) (SR0341.8.9)** process parameter
   (GID-2671245))

      ▪ Last change timestamp per tag from automation layer or **Manual** in case a value has been
      overridden by using the **Override recorded value (SR0341.3.1.2)** user-triggered
      exception (GID-2671806).

5. **Get** button (disabled).

6. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.1.2 Representation in Navigator (SR0341.4+)

The Navigator provides the following details:

2.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>

  - Example:
    Get mixer values

2.1.2.2 GID-2671217 INFORMATION COLUMN (SR0341.4.1)

- <Identifier of affected equipment entity>

  - Example: MixerA12

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

2.1.2.3 ACTION COLUMN

- There are no actions available.

2.1.3 Representation in Sub-report (SR0341.5+)

The sub-report contains the following information:

2.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>

- <Completion time>

- <Unit procedure> / <operation> / <phase>

- <Work center> / <station> / <device> - <phase completion user>

2.1.3.2 GID-2671220 SUB-REPORT ELEMENTS (SR0341.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)

- Instruction text

- Entity (identifier and short description)

In the grid, the phase displays "N/A" for those entries that cannot be provided due to their context (e.g. a unit of measure for a boolean value) or that have not been defined during recipe or workflow design (e.g. a lower limit for a numeric value).

- Table of values that have been read during execution (in the order of the property-specific process parameters).
    - List of boolean properties
        - Identifier
        - Expected value
        - Timestamp
    - List of numeric properties
        - Identifier
        - Limits (LL | L)
        - Value
        - Limits (H | HH)
        - UoM
        - Timestamp
    - List of string properties
        - Identifier
        - Expected value
        - Value
        - Timestamp

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.2 Business Logic (SR0341.2+)

The phase implements the following business logic.

2.2.1 Phase Mode

Business logic related to phase modes.

2.2.1.1 GID-2671221 MANUAL COMPLETION MODE (SR0341.2.1)

- Function: **Manual completion** mode of phase

- Type: Phase mode

- Trigger: Phase becomes active

- Postcondition: Phase is active

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0341.1.2)** layout (GID-2671214).
Operator interaction	20	The **Get** button reads the tag values, see **Get values (SR0341.2.3)** function (GID-2671223). Each time the **Get** button is used, all of the tag values are read unless they have already been read or overridden.
Phase completion	30	See **Confirm phase (SR0341.2.4)** function (GID-2671224).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.2.1.2 GID-2671222 AUTOMATIC COMPLETION MODE (SR0341.2.2)

- Function: **Automatic completion** mode of phase

- Type: Phase mode

- Trigger: Phase becomes active

- Postcondition: Phase is active

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0341.1.2)** layout (GID-2671214).
Phase gets values	20	See **Get values (SR0341.2.3)** function (GID-2671223). - If no error has occurred, continue with the **Confirm phase (SR0341.2.4)** function (GID-2671224). - If an error or warning has occurred, phase must be completed manually. See **Manual completion (SR0341.2.1)** mode (GID-2671221).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.2.2 Main Path

Business logic related to the main path:

2.2.2.1 GID-2671223 GET VALUES (SR0341.2.3)

- Function: Read tag values

- Type: Main path

- Trigger: Operator gets values or **Automatic completion (SR0341.2.2)** mode (GID-2671222)is active

- Postcondition: Phase is active

Step	#	Description
Phase checks manual override	10	If a value has been overridden with the **Override recorded value (Boolean property) (SR0341.3.1.3)** user-triggered exception (GID-2671802), **Override recorded value (Numeric property) (SR0341.3.1.1)** user-triggered exception (GID-2671804), or **Override recorded value (String property) (SR0341.3.1.2)** user-triggered exception (GID-2671806)and the exception has been signed, the **Get** action cannot be executed for such a value; phase displays **Override value recorded (SR0341.3.4.1)** information message (GID-2669431).
Phase checks for read tag values	15	If a tag value has already been read from the automation layer, the **Get** action is not executed for the value.
Phase gets values	20	Phase reads the remaining tag values and disables the **Get** button as soon as there are no tag values that have not yet been read or overridden. The order of the **Boolean property - Master (bundle identifier) (SR0341.8.12)** process parameters (GID-2671234), **Numeric property - Master (bundle identifier) (SR0341.8.5)** process parameters (GID-2671239), and **String property - Master (bundle identifier) (SR0341.8.9)** process parameters (GID-2671245)defines the read sequence of property tag values. Process parameters without property types are skipped. If one of the following issues occurs, phase behavior is as follows:

Step	#	Description
Property cannot be read due to a pre-reading issue	20.1	- Phase does not display a value, - changes cell background to red, - appends "(X)" to the "empty value", and - displays **Invalid configuration error (SR0341.3.6.1)** error message (GID-2671256)
Property cannot be read due to an automation integration issue or tag data quality is rated as bad	20.2	- Phase does not display a value, - changes cell background to red, - appends "(X)" to the "empty value", and - displays **System error (SR0341.3.6.4)** error message (GID-2671258), **No get result error (SR0341.3.6.5)** error message (GID-2671259), or **Automation error (SR0341.3.6.3)** error message (GID-2671257).
Validation	20.3	If a check is violated, phase changes cell background to yellow. After the exception has been signed, phase changes cell background to the default and adds the exception marker to the value's cell. If no check is violated, phase returns to the **Active mode (SR0341.1.2)** layout (GID-2671214). **Boolean Property Bundle** Phase checks the boolean value against the settings of the **Expected value definition (SR0341.8.14)** process parameter (GID-2671237). If the check is violated, phase creates the **Limit violation (SR0341.3.2.1)** system-triggered exception (GID-2671249)for a boolean value. **Numeric Property Bundle** Phase checks the numeric value against the settings of the **Limit definition (SR0341.8.8)** process parameter (GID-2671243). Limits are checked in the following order: LL/HH » L/H. If the check is violated, phase creates the **Limit violation (SR0341.3.2.1)** system-triggered exception (GID-2671249)for a numeric value. **String Property Bundle** Phase checks the string value against the settings of the **Expected value definition (SR0341.8.11)** process parameter (GID-2671248). If the check is violated, phase creates the **Limit violation (SR0341.3.2.1)** system-triggered exception (GID-2671249)for a string value.

Step	#	Description
	30	If applicable, continue with the **Override recorded value (Boolean property) (SR0341.3.1.3)** user-triggered exception (GID-2671802), **Override recorded value (Numeric property) (SR0341.3.1.1)** user-triggered exception (GID-2671804), or **Override recorded value (String property) (SR0341.3.1.2)** user-triggered exception (GID-2671806). Phase can be completed with the **Confirm phase (SR0341.2.4)** function (GID-2671224).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.2.2.2 GID-2671224 CONFIRM PHASE (SR0341.2.4)

- Function: Completion of phase

- Type: Main path

- Trigger: Operator confirms phase or **Automatic completion (SR0341.2.2)** mode (GID-2671222) is active

- Postcondition: Phase is completed

Step	#	Description
In **Manual completion (SR0341.2.1)** mode (GID-2671221)): Operator confirms phase	10	Operator confirms the tag values.

Step	#	Description
Phase performs completion checks	20	If one of the following issues occurs, phase cannot be completed: ▪ In **Manual completion (SR0341.2.1)** mode (GID-2671221), the **Get** button has not been used. ▪ Not all values whose tags are enabled have been read. Phase displays **Recorded values incomplete (SR0341.3.6.7)** error message (GID-2671260). If a validation check fails, phase creates the **Limit violation (SR0341.3.2.1)** system-triggered exception (GID-2671249).
Phase completion	30	Phase is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.3 Process Parameters (SR0341.8+)

The following process parameters define the behavior of the phase.

2.3.1 Instruction Table-specific Parameters

2.3.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

2.3.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. **Restriction**: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

2.3.2 Instruction Link-specific Parameters

2.3.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Instruction text	HTML text	Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2671228). Example: Refer to {SOP1270} for guidance. Maximum length is 2000 characters (including HTML tags).

2.3.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.

Attribute	Type	Comment
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

2.3.3 Basic Parameters

2.3.3.1 GID-2671229 INSTRUCTION (SR0341.8.1)

Attribute	Type	Comment
Text	HTML text	Instruction text to be displayed. **Restriction**: Maximum length is 4000 characters (including HTML tags).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.3.3.2 GID-2671230 IDENTIFIED EQUIPMENT ENTITY (SR0341.8.2)

Attribute	Type	Comment
Equipment object	Reference	Reference to the output of a preceding phase that provides an identified equipment entity.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.3.3.3 GID-2671231 MODE (SR0341.8.3)

Attribute	Type	Comment
Mode	Choice list	Defines the processing mode. **Manual completion** (default): Operator confirms the phase. **Automatic completion**: Phase automatically gets the property values and is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.3.4 Configuration of User-triggered Exceptions

2.3.4.1 GID-2671232 OVERRIDE RECORDED VALUE (SR0341.8.4)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).** Default setting: **High.**
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Override recorded value (Numeric property bundle) (SR0341.3.1.1)** user-triggered exception (GID-2671804), **Override recorded value (Boolean property bundle) SR0341.3.1.3)** user-triggered exception (GID-2671802), and **Override recorded value (String property bundle) (SR0341.3.1.2)** user-triggered exception (GID-2671806).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.3.5 Boolean Property Bundle

2.3.5.1 BUNDLE PROCESS PARAMETERS (FRAMEWORK CAPABILITY)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2667986).

2.3.5.2 GID-2671234 MASTER (BUNDLE IDENTIFIER) (SR0341.8.12)

Attribute	Type	Comment
Property	String	Equipment property to be read.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.3.5.3 PROPERTY SELECTION EDITOR (FRAMEWORK CAPABILITY)

The system provides a Property Selection editor for selecting an equipment property based on its data type (numeric, string, boolean). The supported data types depend on the process parameter.

2.3.6 Configuration of System-triggered Exceptions

2.3.6.1 GID-2671236 EXPECTED VALUE CONFIGURATION (SR0341.8.13)

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the **Value** attribute of the **Expected value definition** process parameter (GID-2671236)is set. If it is not set, the validation will fail. Default setting: **No**.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Override recorded value (SR0341.3.1.3)** user-triggered exception (GID-2671802)and **Limit violation (SR0341.3.2.1)** system-triggered exception (GID-2671249).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.3.6.2 GID-2671237 EXPECTED VALUE DEFINITION (SR0341.8.14)

Attribute	Type	Comment
Value	Choice list	Defines the expected value. Available settings: **N/A, Yes, No.** Default setting: **N/A.**

See also **Override recorded value (SR0341.3.1.3)** user-triggered exception (GID-2671802) and **Limit violation (SR0341.3.2.1)** system-triggered exception (GID-2671249).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.3.7 Numeric Property Bundle

2.3.7.1 BUNDLE PROCESS PARAMETERS (FRAMEWORK CAPABILITY)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2667986).

2.3.7.2 GID-2671239 MASTER (BUNDLE IDENTIFIER) (SR0341.8.5)

Attribute	Type	Comment
Property	String	Equipment property to be read.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.3.7.3 PROPERTY SELECTION EDITOR (FRAMEWORK CAPABILITY)

The system provides a Property Selection editor for selecting an equipment property based on its data type (numeric, string, boolean). The supported data types depend on the process parameter.

2.3.8 Configuration of System-triggered Exceptions

2.3.8.1 GID-2671241 L-H CONFIGURATION (SR0341.8.6)

If the checks are activated for the available limit ranges, the checks are performed in the following order:

1. LL-HH (defined with the **LL-HH configuration (SR0341.8.7)** process parameter (GID-2671242))

2. L-H

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the **L limit** or **H limit** attributes of the **Limit definition** process parameter link are set. If they are not set, the validation will fail. Default setting: **No.**
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High.**
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Override recorded value (SR0341.3.1.1)** user-triggered exception (GID-2671804)and **Limit violation (SR0341.3.2.1)** system-triggered exception (GID-2671249).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.3.8.2 GID-2671242 LL-HH CONFIGURATION (SR0341.8.7)

If the checks are activated for the available limit ranges, the checks are performed in the following order:

1. LL-HH

2. L-H (defined with the **L-H configuration (SR0341.8.6)** process parameter [(GID-2671241)](#))

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the **LL limit** or **HH limit** attributes of the **Limit definition** process parameter [(GID-2671243)](#)are set. If they are not set, the validation will fail. Default setting: **No.**
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High.**
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Override recorded value (SR0341.3.1.1)** user-triggered exception [(GID-2671804)](#)and **Limit violation (SR0341.3.2.1)** system-triggered exception [(GID-2671249)](#).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.3.8.3 GID-2671243 LIMIT DEFINITION (SR0341.8.8)

The following rule applies to the attributes:

▪ LL limit < L limit < H limit < HH limit

Attribute	Type	Comment
LL limit	BigDecimal (Double, Float, Integer)	Define the values of the lower limits (including the values themselves).
L limit	BigDecimal (Double, Float, Integer)	
H limit	BigDecimal (Double, Float, Integer)	Define the values of the upper limits (including the values themselves).
HH limit	BigDecimal (Double, Float, Integer)	

See also **Override recorded value (SR0341.3.1.1)** user-triggered exception (GID-2671805)and **Limit violation (SR0341.3.2.1)** system-triggered exception (GID-2671249).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.3.9 String Property Bundle

2.3.9.1 BUNDLE PROCESS PARAMETERS (FRAMEWORK CAPABILITY)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2667986).

2.3.9.2 GID-2671245 MASTER (BUNDLE IDENTIFIER) (SR0341.8.9)

Attribute	Type	Comment
Property	String	Equipment property to be read.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.3.9.3 PROPERTY SELECTION EDITOR (FRAMEWORK CAPABILITY)

The system provides a Property Selection editor for selecting an equipment property based on its data type (numeric, string, boolean). The supported data types depend on the process parameter.

2.3.10 Configuration of System-triggered Exceptions

2.3.10.1 GID-2671247 EXPECTED VALUE CONFIGURATION (SR0341.8.10)

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the **Value** attribute of the **Expected value definition** process parameter (GID-2671248)is set. If it is not set, the validation will fail. Default setting: **No.**
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).** Default setting: **High.**
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Override recorded value (SR0341.3.1.2)** user-triggered exception (GID-2671806)and **Limit violation (SR0341.3.2.1)** system-triggered exception (GID-2671249).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.3.10.2   GID-2671248 EXPECTED VALUE DEFINITION (SR0341.8.11)

Attribute	Type	Comment
Value	Text	Defines the expected value. Maximum length is 2000 characters.

> See also **Override recorded value (SR0341.3.1.2)** user-triggered exception (GID-2671806)and **Limit violation (SR0341.3.2.1)** system-triggered exception (GID-2671249).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.4 Exceptions (SR0341.3+)

The phase supports user-defined, user-triggered (GID-2669429), system-triggered (GID-2669429), and post-completion exceptions (GID-2669430) and their configuration by means of process parameters (GID-2668220).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

2.4.1 System-triggered Exceptions (SR0341.3.2+)

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

2.4.1.1 GID-2671249 LIMIT VIOLATION (SR0341.3.2.1)

If several checks fail during the execution of the **Get** action, the exceptions are combined and displayed in a single exception. The highest risk assessment of all related exceptions and its related signature privilege apply.

Representation of the exception:

▪ A violation of limits or expected values has occurred.

- List of up to 50 property types in the order of the property-specific process parameters:

  - **Boolean Property Bundle**:
    Exception text:
    <Exception text>
    (taken from **Expected value configuration (SR0341.8.13)** process parameter (GID-2671236))
    Property: <property identifier>
    Expected value <expected value>
    (taken from **Expected value definition (SR0341.8.14)** process parameter (GID-2671237))
    Actual value: <OPC value>

    - Example:
      Expected value violation confirmed.
      Property: HeatingPerformed
      Expected value: Yes
      Actual value: No

  - **Numeric Property Bundle**:
    Exception text:
    <Exception text>
    (taken from **L-H configuration (SR0341.8.6)** process parameter (GID-2671241)or **LL-HH configuration (SR0341.8.7)** process parameter link)
    Property: <property identifier>
    <Affected limit, L, LL, H, HH>: <limit value>
    (taken from **Limit definition (SR0341.8.8)** process parameter (GID-2671243))
    Actual value: <OPC value>

    - Example:
      Limit violation confirmed.
      Property: AgitatorSpeed
      LL limit: 300 rpm
      Actual value: 200 rpm

  - **String Property Bundle**:
    Exception text:
    <Exception text>
    (taken from **Expected value configuration (SR0341.8.10)** process parameter (GID-2671247))
    Property: <property identifier>
    Expected value: <expected value>
    (taken from **Expected value definition (SR0341.8.11)** process parameter (GID-2671248))
    Actual value: <OPC value>

■ Example:
Expected value violation confirmed.
Property: VisualCheckResult
Expected value: Dark blue
Actual value: Light blue

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

2.4.1.2 GID-2671250 LIMIT VIOLATION - LOGIC (SR0341.3.2.1.1)

■ Trigger: Check has failed

■ Postcondition: Exception is recorded

Step	#	Description
Operator accepts exceptional situation	10	Phase shows exception description to be signed.
Operator signs exception	20	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

2.4.1.3 GID-2671251 MULTIPLE SYSTEM-TRIGGERED EXCEPTIONS (SR0341.3.2.2)

In case multiple system-triggered exceptions occur, only one combined exception (system-triggered exception) is recorded including information about all exceptions. The highest risk assessment of all related exceptions and its related signature privilege apply.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

2.4.2 User-triggered Exceptions (SR0341.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

2.4.2.1 BOOLEAN PROPERTY BUNDLE

2.4.2.1.1 GID-2671802 OVERRIDE RECORDED VALUE (SR0341.3.1.3)

The **Override recorded value** exception allows an operator to override the boolean value read from the entity.

There is one exception per boolean property.
Properties for which an error has been detected are displayed at the top of the list properties.

Representation during exception handling:

- Instruction:
  Override the recorded value:
  Current value: <current value>
  New value: <value>
  Confirm button.

- Exception text:
  <Exception text>
  (taken from **Override recorded value (SR0341.8.4)** process parameter (GID-2671232))
  Property: <property identifier>
  Old value: <old value>
  New value: <new value>

  - Example:
    Value overridden.
    Property: Infrared sensor on
    Old value: True
    New value: False

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

2.4.2.1.2 GID-2671803 Override recorded value - Logic (SR0341.3.1.3.1)

- Trigger: Exception is selected

- Postcondition: Boolean value is set

Step	#	Description
Operator triggers exception	10	Phase displays Exception Window.
	20	Operator selects value.
Operator confirms exception	30	If the check is enabled, phase checks the boolean value against the settings of the **Expected value definition (SR0341.8.14)** process parameter (GID-2671237).
	30.1	If the expected value is violated, phase displays a corresponding message dialog with an **Exception** button, the exception text (taken from **Expected value configuration (SR0341.8.13)** process parameter (GID-2671236)), the property identifier, the affected limit, and the actual value.
Operator accepts exceptional situation	30.1.1	Phase displays only one combined exception (user-triggered exception), including both exception texts from the override-value-exception and from the violation of the expected value (see **Limit violation (SR0341.3.2.1)** system-triggered exception (GID-2671249)for a boolean value).
Operator cancels exceptional situation	30.1.2	Phase requires the operator to sign an **Exception canceled** exception and then allows the operator to return to the user-triggered exception view (Step 20).
	30.2	If the expected value is not violated or no check applies, the override value-related exception is displayed.
	30.3	If the following issue occurs, phase displays an error message: - Override value is missing, **No value overridden (SR0342.3.6.11)** error message (GID-2671817). Phase shows exception description to be signed according to **Override recorded value (SR0341.8.4)** process parameter (GID-2671232).
Operator signs exception	40	Phase records the exception. Additionally, phase adds the exception marker to the value's cell in the **Active mode (SR0341.1.2)** layout (GID-2671214).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

2.4.2.2 NUMERIC PROPERTY BUNDLE

2.4.2.2.1 GID-2671804 OVERRIDE RECORDED VALUE (SR0341.3.1.1)

The **Override recorded value** exception allows an operator to override the numeric value read from the entity.

There is one exception per numeric property.
Properties for which an error has been detected are displayed at the top of the list properties.

Representation during exception handling:

- Instruction:
  Override the recorded value:
  Current value: <current value> <UoM>
  New value: <new value> <UoM>
  Confirm button.

- Exception text:
  <Exception text>
  (taken from **Override recorded value (SR0341.8.4)** process parameter (GID-2671232))
  Property: <property identifier>
  Old value: <value> <UoM>
  New value: <value> <UoM>

  - Example:
    Value overridden.
    Property: AgitatorSpeed
    Old value: 12.43 rpm
    New value: 12.93 rpm

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

2.4.2.2.2 GID-2671805 Override recorded value - Logic (SR0341.3.1.1.1)

- Trigger: Exception is selected

- Postcondition: Numeric value is set

Step	#	Description
Operator triggers exception	10	Phase displays Exception Window.
	20	Operator enters values. If the following issue occurs, phase displays an error message: - Data format does not match, **Invalid data format error (SR0341.3.6.8)** error message (GID-2671261).
Operator confirms exception	30	If the related check is enabled, phase checks the numeric value against the settings of the **Limit definition (SR0341.8.8)** process parameter (GID-2671243). Limits are checked in the following order: LL/HH » L/H.
	30.1	If a limit is violated, phase displays a corresponding message dialog with an **Exception** button, the exception text (taken from **L-H configuration (SR0341.8.6)** process parameter (GID-2671241)or **LL-HH configuration (SR0341.8.7)** process parameter (GID-2671242)), the property identifier, the affected limit, and the actual value.
Operator accepts exceptional situation	30.1.1	Phase displays only one combined exception (user-triggered exception), including both exception texts from the override-value-exception and from the limit violation (see **Limit violation (SR0341.3.2.1)** system-triggered exception (GID-2671249)for a numeric value).
Operator cancels exceptional situation	30.1.2	Phase requires the operator to sign an **Exception canceled** exception and then allows the operator to return to the user-triggered exception view (Step 20).
	30.2	If no limit is violated or no check applies, the override value-related exception is displayed.
	30.3	If the following issue occurs, phase displays an error message: - Override value is missing, **No value overridden (SR0341.3.6.9)** error message (GID-2671263) Phase shows exception description to be signed according to **Override recorded value (SR0341.8.4)** process parameter (GID-2671232).

Step	#	Description
Operator signs exception	40	Phase records the exception. Additionally, phase adds the exception marker to the value's cell in the **Active mode (SR0341.1.2)** layout (GID-2671214).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

2.4.2.3 STRING PROPERTY BUNDLE

2.4.2.3.1 GID-2671806 OVERRIDE RECORDED VALUE (SR0341.3.1.2)

The **Override recorded value** exception allows an operator to override the string value read from the entity.

There is one exception per string property.
Properties for which an error has been detected are displayed at the top of the list properties.

Representation during exception handling:

- Instruction:
  Override the recorded value:
  Current value: <current value>
  New value: <value>
  Confirm button.

- Exception text:
  <Exception text>
  (taken from **Override recorded value (SR0341.8.4)** process parameter (GID-2671232))
  Property: <property identifier>
  Old value: <old value>
  New value: <new value>

  - Example:
    Value overridden.
    Property: HeatingPerformed
    Old value: Temperature alarm
    New value: High temperature alarm

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

2.4.2.3.2 GID-2671807 Override recorded value - Logic (SR0341.3.1.2.1)

- Trigger: Exception is selected

- Postcondition: String value is set

Step	#	Description
Operator triggers exception	10	Phase displays Exception Window.
	20	Operator enters value.
Operator confirms exception	30	If the related check is enabled, phase checks the string value against the settings of the **Expected value definition (SR0341.8.11)** process parameter (GID-2671248).
	30.1	If the expected value is violated, phase displays a corresponding message dialog with an **Exception** button, the exception text (taken from **Expected value configuration (SR0341.8.10)** process parameter (GID-2671247)), the property identifier, the affected limit, and the actual value.
Operator accepts exceptional situation	30.1.1	Phase displays only one combined exception (user-triggered exception), including both exception texts from the override-value-exception and from the violation of the expected value (see **Limit violation (SR0341.3.2.1)** system-triggered exception (GID-2671249)for a string value).
Operator cancels exceptional situation	30.1.2	Phase requires the operator to sign an **Exception canceled** exception and then allows the operator to return to the user-triggered exception view (Step 20).
	30.2	If the expected value is not violated or no check applies, the override value-related exception is displayed.
	30.3	If the following issue occurs, phase displays an error message: - Override value is missing, **No value overridden (SR0341.3.6.10)** error message (GID-2671264). Phase shows exception description to be signed according to **Override recorded value (SR0341.8.4)** process parameter (GID-2671232).
Operator signs exception	40	Phase records the exception. Additionally, phase adds the exception marker to the value's cell in the **Active mode (SR0341.1.2)** layout (GID-2671214).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

2.4.2.4 NOT BUNDLE-SPECIFIC

2.4.2.4.1 GID-2671808 MULTIPLE EXCEPTIONS (SR0341.3.1.4)

In case an **Override recorded value (Numeric property) (SR0341.3.1.1)** user-triggered exception (GID-2671804), **Override recorded value (String property) (SR0341.3.1.2)** user-triggered exception (GID-2671806), or **Override recorded value (Boolean property) (SR0341.3.1.3)** user-triggered exception (GID-2671802)coincides with the **Limit violation (SR0341.3.2.1)** system-triggered exception (GID-2671249), only one combined exception (user-triggered exception) is recorded including information about all related exceptions. The highest risk assessment of all related exceptions and its related signature privilege apply.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

2.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

2.5 Information Messages (SR0341.3.4+)

Information messages are represented in an information dialog containing a message type-specific icon, the information message, and an **OK** button.

The following information messages are available to inform the operator about how to proceed.

2.5.1 GID-2669431 Override value recorded (SR0341.3.4.1)

UI text	Comment
▪ The Get action was not successful. ▪ <empty string> ▪ Values have already been overridden manually. ▪ <list of tags>	▪ Message pack: PhaseEqmAIGetOPCValues<version> Message ID: ExecutionError_HeaderMsg ▪ Message pack: PhaseEqmAIGetOPCValues<version> Message ID: BusinessLogic_ErrorCategory ▪ Message pack: PhaseEqmAIGetOPCValues<version> Message ID: ValuesOverridden_WarningCategory ▪ Message pack: PhaseEqmAIGetOPCValues<version> Message ID: ReadPostcheck_NoGetAfterOverride_ErrorMsg

UI text	Comment
	Potential error cause: **Get** button is used after the **Override recorded value (Boolean property) (SR0341.3.1.3)** user-triggered exception (GID-2671802), **Override recorded value (Numeric property) (SR0341.3.1.1)** user-triggered exception (GID-2671804), or **Override recorded value (String property) (SR0341.3.1.2)** user-triggered exception (GID-2671806)has been signed.

The **Details** button provides access to more specific technical information.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.6 Questions

There are no questions available.

2.7 Decisions

There are no decisions available.

2.8 Error Messages (SR0341.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

They are composed of up to three levels:

1. header,

2. category, and

3. details (not always used).

The following error messages are available to inform the operator about error conditions.

2.8.1 Get Property-specific Error Messages (Pre-reading)

2.8.1.1 GID-2671256 INVALID CONFIGURATION ERROR (SR0341.3.6.1)

UI text	Comment
▪ The Get action was not successful. ▪ Please record the values manually.	▪ Message pack: PhaseEqmAIGetOPCValues<version> Message ID: CheckBeforeExecuteError_HeaderMsg ▪ Message pack: PhaseEqmAIGetOPCValues<version> Message ID: IrreparableExecution_ErrorCategory

UI text	Comment
	Potential error cause: ▪ Tag is enabled, but the tag path is undefined. ▪ The property to be read is not defined for the identified equipment entity.

The **Details** button provides access to more specific technical information.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.8.1.2 GID-2671257 AUTOMATION ERROR (SR0341.3.6.3)

UI text	Comment
▪ The Get action was not successful. ▪ Please record the values manually.	▪ Message pack: PhaseEqmAIGetOPCValues<version> Message ID: ExecutionError_HeaderMsg ▪ Message pack: PhaseEqmAIGetOPCValues<version> Message ID: IrreparableExecution_ErrorCategory Potential error cause: ▪ Referenced equipment entity is undefined (Null). ▪ The quality of the read tag value is rated as bad.

The **Details** button provides access to more specific technical information.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.8.2 Get Property-specific Error Messages (Reading)

2.8.2.1 GID-2671258 SYSTEM ERROR (SR0341.3.6.4)

UI text	Comment
▪ The Get action was not successful. ▪ Please record the values manually.	▪ Message pack: PhaseEqmAIGetOPCValues<version> Message ID: ExecutionError_HeaderMsg ▪ Message pack: PhaseEqmAIGetOPCValues<version> Message ID: Other_ErrorCategory

UI text	Comment
	Potential error cause: ▪ Automation Integration server cannot be reached. ▪ Automation Integration server read failure. ▪ Live Data server read failure. ▪ The quality of the read tag value is rated as bad.

The **Details** button provides access to more specific technical information.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.8.2.2 GID-2671259 NO GET RESULT ERROR (SR0341.3.6.5)

UI text	Comment
▪ The Get action was not successful. ▪ Please record the values manually.	▪ Message pack: PhaseEqmAIGetOPCValues\<version\> Message ID: ExecutionError_HeaderMsg ▪ Message pack: PhaseEqmAIGetOPCValues\<version\> Message ID: IrreparableExecution_ErrorCategory Potential error cause: ▪ The return value of the Automation Integration server does not contain an entry for at least one defined and valid property tag path. ▪ The quality of the read tag value is rated as bad. ▪ Health, simulation, or maintenance verification failed.

The **Details** button provides access to more specific technical information.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.8.3 Phase Completion-specific Error Messages

2.8.3.1 GID-2671260 RECORDED VALUES INCOMPLETE (SR0341.3.6.7)

UI text	Comment
▪ Cannot confirm. ▪ Not all expected values have been recorded. Please record the values manually.	▪ Message pack: PhaseEqmAIGetOPCValues\<version\> Message ID: CompletionError_HeaderMsg ▪ Message pack: PhaseEqmAIGetOPCValues\<version\> Message ID: ReparableConfirm_ErrorCategory Potential error cause: The values of the enabled tags were not read successfully or overridden. Expected values are still missing.

The **Details** button provides access to more specific technical information.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.8.4 User-triggered Exception-specific Error Messages

2.8.4.1 GID-2671261 INVALID DATA FORMAT ERROR (SR0341.3.6.8)

▪ Applies to Numeric Property Bundle only

UI text	Comment
▪ Cannot confirm the overridden values. ▪ \<empty string\>	▪ Message pack: PhaseEqmAIGetOPCValues\<version\> Message ID: OverrideExceptionConfirmationError_HeaderMsg ▪ Message pack: PhaseEqmAIGetOPCValues\<version\> Message ID: Other_ErrorCategory Potential error cause: The entered text value cannot be converted to a numeric value of the targeted numeric data type.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.8.5 Boolean Property Bundle

2.8.5.1 GID-2671262 NO VALUE OVERRIDDEN (SR0341.3.6.11)

UI text	Comment
▪ You have to select a value before you can confirm.	▪ Message pack: PhaseEqmAI\<version\> Message ID: OverrideBooleanValueNotSet_ErrorMsg Potential error cause: No override value was selected before the user-triggered exception was confirmed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.8.6 Numeric Property Bundle

2.8.6.1 GID-2671263 NO VALUE OVERRIDDEN (SR0341.3.6.9)

UI text	Comment
▪ Enter an override value.	▪ Message pack: PhaseEqmAI\<version\> Message ID: OverrideNumericValueNotSet_ErrorMsg Potential error cause: No override value was entered before the user-triggered exception was confirmed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.8.7 String Property Bundle

2.8.7.1 GID-2671264 NO VALUE OVERRIDDEN (SR0341.3.6.10)

UI text	Comment
▪ You have to enter an override value before you can confirm.	▪ Message pack: PhaseEqmAI\<version\> Message ID: OverrideStringValueNotSet_ErrorMsg Potential error cause: No override value was entered before the user-triggered exception was confirmed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.9 Output Variables (SR0341.9+)

The following output variables are available to reference the phase's output.

2.9.1 Instance count (Framework capability)

- Data type: Long

- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

2.9.2 Start time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the start time of the phase.

2.9.3 Completion time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the completion time of the phase.

2.9.4 Identifier (Framework capability)

- Data type: String

- Usage: The output variable provides the identifier of the phase.

2.9.5 GID-2669443 Automation get successful (SR0341.9.1)

- Data type: Boolean

- Values: true, false

- Usage: The output variable states if the get operation from the automation layer was successful.

  - The value is true if all property values have been read successfully.

  - The value is false if at least one of the property values could not be read from the automation layer or has been overridden by using the **Override recorded value (Numeric property) (SR0341.3.1.1)** user-triggered exception (GID-2671804), **Override recorded value (String property) (SR0341.3.1.2)** user-triggered exception (GID-2671806), or **Override recorded value (Boolean property) (SR0341.3.1.3)** user-triggered exception (GID-2671802).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.9.6 Boolean Property Bundle

Bundle output variable (Framework capability)

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2667986).

2.9.6.1 GID-2671265 VALUE (SR0341.9.9)

- Data type: Boolean

- Usage: The output variable provides the value of the boolean property tag. The value is Null if N/A is the phase result.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.9.6.2 GID-2671266 AUTOMATION GET SUCCESSFUL (SR0341.9.10)

- Data type: Boolean

- Values: true, false

- Usage: The output variable states if the get operation from the automation layer was successful.

    - The value is true if the property value of the boolean property has been read successfully.

    - The value is false if the property value of the boolean property could not be read from the automation layer or has been overridden by using the **Override recorded value (SR0341.3.1.3)** user-triggered exception (GID-2671802).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.9.7 Numeric Property Bundle

2.9.7.1 BUNDLE OUTPUT VARIABLE (FRAMEWORK CAPABILITY)

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2667986).

2.9.7.2 GID-2671268 VALUE (SR0341.9.2)

- Data type: BigDecimal

- Usage: The output variable provides the actual value of the numeric property tag as a **BigDecimal** value. The value is Null if N/A is the phase result.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.9.7.3 GID-2671269 UNIT OF MEASURE (SR0341.9.3)

- Data type: String

- Usage: The output variable provides the unit of measure of the numeric property tag. The value is Null if N/A is the phase result.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.9.7.4 GID-3077447 AUTOMATION GET SUCCESSFUL (SR0341.9.4)

- Data type: Boolean

- Values: true, false

- Usage: The output variable states if the get operation from the automation layer was successful.

  - The value is true if the property value of the numeric property has been read successfully.

- Override recorded value (SR0341.3.1.1) user-triggered exception (GID-2671804).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.9.8 String Property Bundle

2.9.8.1 BUNDLE OUTPUT VARIABLE (FRAMEWORK CAPABILITY)

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2667986).

2.9.8.2 GID-2671272 VALUE (SR0341.9.6)

- Data type: String

- Usage: The output variable provides the value of the string property tag. The value is Null if N/A is the phase result.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.9.8.3 GID-2671273 AUTOMATION GET SUCCESSFUL (SR0341.9.7)

- Data type: Boolean

- Values: true, false

- Usage: The output variable states if the get operation from the automation layer was successful.

    - The value is true if the property value of the string property has been read successfully.

    - The value is false if the property value of the string property could not be read from the automation layer or has been overridden by using the **Override recorded value (SR0341.3.1.2)** user-triggered exception (GID-2671806).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.10 Performance (SR0341.12+)

2.10.1 GID-2669447 Performance of Get Activity (SR0341.12.1)

The time for getting the OPC values on the automation layer does not take longer than 5 seconds. Any potential delay by the OPC server or the PLC communication is not considered.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

3 Set OPC Values Phase (SR0342+)

The **Set OPC values** phase allows to write up to 50 tag values of one equipment entity to the automation layer. It supports the following data types:

- BigDecimal Value (Double, Float, Integer) with low and high limits,
- Boolean Value: choice between Yes and No (true and false), and
- String Value.

An example use cases is:

- Set up parameters of a mixer
  With one button tap, an operator can transfer the values of all relevant set points of a mixer to the automation layer:

  - Mixer speed = 500 (rpm), specification limit low = 400 rpm, specification limit high = 1000 rpm
  - HeatingControl = Yes
  - HeatingTargetTemp = 55 °C
  - HeatingProfile = 7
  - HMI_InstructionText1 = Control visual foam situation

Different phase modes enable the usage in various situations that can occur during processing:

- In the **Manual completion** mode, the operator manually sets the values.
- In the **Automatic completion** mode, the phase sets the values and is completed automatically without any operator interaction.

The affected equipment entity, the affected properties, and their values are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2669450).

Anomalies that occur during processing are covered by the phase exception handling (GID-2671284) (e.g. equipment entity is not available).

After completion the phase displays the affected properties and their values in the Execution Window.

The Navigator displays the identifier of the affected equipment entity.

Download the setpoints to the tablet press.

Entity: TabletPress_AM / Automated Tablet Press

Property	Low	Value	High	UoM	Automation set
Compressing Force	65	70	75		☐
Tablet Dimensions	8.8	9	9.2	mm	☐
Tablet Form		Yes			☐
Batch ID (TP)		BX59			☐

Set Confirm

Figure 2: Set OPC values during execution

3.1 Layout

The phase provides individual layouts for its representation during execution (GID-2669448), in the Navigator (GID-2669449), and in the sub-report (GID-2669450).

3.1.1 Representation during Execution (SR0342.1+)

The representation during execution depends on the phase mode.

3.1.1.1 GID-2671274 PREVIEW MODE (SR0342.1.1)

1. <Instruction text>
   (taken from **Instruction (SR0342.8.1)** process parameter (GID-2671290))

2. Entity:

3. List of up to 50 property types in the order of the property-specific process parameters:

   - **Boolean Property Bundle:**
     List of boolean properties
     (taken from **Boolean property - Master (bundle identifier) (SR0342.8.8)** process parameter (GID-2671296))

     - Read-only checkbox to indicate if the values have been successfully set on the automation layer.

   - **Numeric Property Bundle:**
     List of numeric properties
     (taken from **Numeric property - Master (bundle identifier) (SR0342.8.6)** process parameter (GID-2671299))

     - Read-only checkbox to indicate if the values have been successfully set on the automation layer.

- **String Property Bundle:**
  List of string properties
  (taken from **String property - Master (bundle identifier) (SR0342.8.7)** process parameter (GID-2671302))

  - Read-only checkbox to indicate if the values have been successfully set on the automation layer.

4. **Set** button (disabled).

5. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

3.1.1.2 GID-2671275 ACTIVE MODE (SR0342.1.2)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0342.8.1)** process parameter (GID-2671290))

3. Entity: <equipment entity identifier> / <equipment entity short description>
   (taken from **Identified equipment entity (SR0342.8.2)** process parameter (GID-2671291))

4. List of up to 50 property types in the order of the property-specific process parameters:

   - **Boolean Property Bundle:**
     List of boolean properties
     (taken from **Boolean property - Master (bundle identifier) (SR0342.8.8)** process parameter (GID-2671296))

     - For the representation of the value, see **Set values (SR0342.2.3)** function (GID-2671284).

     - Read-only checkbox to indicate if the values have been successfully set on the automation layer.

   - **Numeric Property Bundle:**
     List of numeric properties
     (taken from **Numeric property - Master (bundle identifier) (SR0342.8.6)** process parameter (GID-2671299))

     - For the representation of the value, see **Set values (SR0342.2.3)** function (GID-2671284).

     - Read-only checkbox to indicate if the values have been successfully set on the automation layer.

- **String Property Bundle:**
  List of string properties
  (taken from **String property - Master (bundle identifier) (SR0342.8.7)** process parameter (GID-2671302))

  - For the representation of the value, see **Set values (SR0342.2.3)** function (GID-2671284).

  - Read-only checkbox to indicate if the values have been successfully set on the automation layer.

5. **Set** button.

6. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.1.1.3 GID-2671276 COMPLETED MODE (SR0342.1.3)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0342.8.1)** process parameter (GID-2671290))

3. Entity: <equipment entity identifier> / <equipment entity short description>
   (taken from **Identified equipment entity (SR0342.8.2)** process parameter (GID-2671291))

4. List of up to 50 property types in the order of the property-specific process parameters:

   - **Boolean Property Bundle:**
     List of boolean properties
     (taken from **Boolean property - Master (bundle identifier) (SR0342.8.8)** process parameter (GID-2671296))

     - Read-only checkbox to indicate if the values have been successfully set on the automation layer.

   - **Numeric Property Bundle:**
     List of numeric properties
     (taken from **Numeric property - Master (bundle identifier) (SR0342.8.6)** process parameter (GID-2671299))

     - Read-only checkbox to indicate if the values have been successfully set on the automation layer.

   - **String Property Bundle:**
     List of string properties
     (taken from **String property - Master (bundle identifier) (SR0342.8.7)** process parameter (GID-2671302))

- Read-only checkbox to indicate if the values have been successfully set on the automation layer.

5. **Set** button (disabled).

6. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.1.2 Representation in Navigator (SR0342.4+)

The Navigator provides the following details:

3.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>

    - Example:
      Set up mixer

3.1.2.2 GID-2671278 INFORMATION COLUMN (SR0342.4.1)

- <Identifier of affected equipment entity>

    - Example: MixerA12

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

3.1.2.3 ACTION COLUMN

- There are no actions available.

3.1.3 Representation in Sub-report (SR0342.5+)

The sub-report contains the following information:

3.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>

- <Completion time>

- <Unit procedure> / <operation> / <phase>

- <Work center> / <station> / <device> - <phase completion user>

3.1.3.2 GID-2671281 Sub-report elements (SR0342.5.1)

< li>Instruction table panel and/or instruction link panel
(only if an instruction table and/or instruction link is defined for the phase)

- Instruction text

- Entity (identifier and short description)

- Table of values that have been set during execution (in the order of the property-specific process parameters).

  - List of boolean properties<

    - Identifier

    - Value

    - Value successfully set on the automation layer (yes, no)

  - List of numeric properties

    - Identifier

    - Low

    - Value

    - High

    - UoM

    - Value successfully set on the automation layer (yes, no)

  - List of string properties

    - Identifier

    - Value

    - Value successfully set on the automation layer (yes, no)

In the grid, the phase displays "N/A" for those entries that cannot be provided due to their context (e.g. a unit of measure for a boolean value) or that have not been defined during recipe or workflow design (e.g. a lower limit for a numeric value).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.2 Business Logic (SR0342.2+)

The phase implements the following business logic.

3.2.1 Phase Mode

Business logic related to phase modes.

3.2.1.1 GID-2671282 MANUAL COMPLETION MODE (SR0342.2.1)

- Function: **Manual completion** mode of phase
- Type: Phase mode
- Trigger: Phase becomes active
- Postcondition: Phase is active

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0342.1.2)** layout (GID-2671275). If any issue related to automation is detected during phase activation, - phase changes the cell background to red and - appends "(X)" to the "empty value".
Operator interaction	20	The **Set** button writes the tag values, see **Set values (SR0342.2.3)** function (GID-2671284).. Each time the **Set** button is used, all of the tag values are written.
Phase completion	30	See **Confirm phase (SR0342.2.4)** function (GID-2671285).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.2.1.2 GID-2671283 AUTOMATIC COMPLETION MODE (SR0342.2.2)

- Function: **Automatic completion** mode of phase
- Type: Phase mode
- Trigger: Phase becomes active
- Postcondition: Phase is active

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0342.1.2)** layout (GID-2671275). If any issue related to automation is detected during phase activation, • phase changes the cell background to red and • appends "(X)" to the "empty value".
Phase sets values	20	See **Set values (SR0342.2.3)** function (GID-2671284). • If no error has occurred, continue with the **Confirm phase (SR0342.2.4)** function (GID-2671285). • If at least one of the values could not be set automatically, phase must be completed manually. See **Manual completion (SR0342.2.1)** mode (GID-2671282).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.2.2 Main Path

Business logic related to the main path:

3.2.2.1 GID-2671284 SET VALUES (SR0342.2.3)

- Function: Write tag values
- Type: Main path
- Trigger: Operator sets values or **Automatic completion (SR0342.2.2)** mode (GID-2671283)is active
- Postcondition: Phase is active

Step	#	Description
Phase checks for "input at equipment"	10	If the **Input at equipment (SR0342.3.1.1)** user-triggered exception (GID-2671304) has been signed before, the **Set** action cannot be executed; phase displays **Input at equipment recorded (SR0342.3.6.2)** error message (GID-2671310).

Step	#	Description
Phase sets values	20	Phase writes the tag values. The order of the **Boolean property - Master (bundle identifier) (SR0342.8.8)** process parameters link , **Numeric property - Master (bundle identifier) (SR0342.8.6)** process parameters (GID-2671299), and **String property - Master (bundle identifier) (SR0342.8.7)** process parameters (GID-2671302)defines the write sequence of property tag values. Process parameters without property types are skipped. If one of the following issues occurs, phase behavior is as follows:
Tag not enabled	20.1	▪ **Boolean Property Bundle** Phase changes cell background to gray. ▪ **Numeric Property Bundle** Phase sets the value to N/A. ▪ **String Property Bundle** Phase changes cell background to gray.
Not all defined automation properties have a value to be set (value is empty or null)	20.2	▪ Phase does not display a value, ▪ changes cell background to red, and ▪ appends "(X)" to the "empty value". If the **Set** button is used, ▪ phase displays **Defined values incomplete (SR0342.3.6.3)** error message (GID-2671311)and ▪ does not perform a tag write operation.
Tag write operation fails due to an automation integration issue	20.3	▪ Phase does not display a value, ▪ does not select read-only checkbox to indicate if the values have been successfully set on the automation layer, ▪ changes cell background of checkbox to red, ▪ appends "(X)" to the "empty value", and ▪ displays **System error (SR0342.3.6.4)** error message (GID-2671312), **Automation error (SR0342.3.6.5)** error message (GID-2671313), or combined error message (**Error message grouping (SR0342.3.6.6)** error message (GID-2671314)).

Step	#	Description
	30	When the operator has confirmed an error message with **OK**, phase returns to the **Active mode (SR0342.1.2)** layout (GID-2671275). If applicable, continue with the **Override value definition (Boolean property) (SR0342.3.1.4)** user-triggered exception (GID-2671809), **Override value definition (Numeric property) (SR0342.3.1.2)** user-triggered exception (GID-2671811), **Override value definition (String property) (SR0342.3.1.3)** user-triggered exception (GID-2671813), or the **Input at equipment (SR0342.3.1.1)** user-triggered exception (GID-2671304).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.2.2.2 GID-2671285 CONFIRM PHASE (SR0342.2.4)

- Function: Completion of phase

- Type: Main path

- Trigger: Operator confirms phase or **Automatic completion (SR0342.2.2)** mode (GID-2671283)is active

- Postcondition: Phase is completed

Step	#	Description
In **Manual completion (SR0342.2.1)** mode (GID-2671282): Operator confirms phase	10	Operator confirms the tag values.

Step	#	Description
Phase performs completion checks	20	If one of the following issues occurs, phase displays an error message: ▪ Defined property values have not been set, **Defined values not set (SR0342.3.6.7)** error message (GID-2671315). ▪ Defined property values have not been set and defined property values are incomplete, combined error message (**Error message grouping - Confirmed (SR0342.3.6.8)** error message (GID-2671316)). When the operator has confirmed an error message with **OK**, phase returns to the **Active mode (SR0342.1.2)** layout (GID-2671275). If applicable, continue with the **Input at equipment (SR0342.3.1.1)** user-triggered exception (GID-2671304).
Phase completion	30	Phase is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3 Process Parameters (SR0342.8+)

The following process parameters define the behavior of the phase.

3.3.1 Instruction Table-specific Parameters

3.3.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

3.3.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. **Restriction**: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

3.3.2 Instruction Link-specific Parameters

3.3.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Instruction text	HTML text	Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter. (GID-2671289) Example: Refer to {SOP1270} for guidance. Maximum length is 2000 characters (including HTML tags).

3.3.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.

Attribute	Type	Comment
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

3.3.3 Basic Parameters

3.3.3.1 GID-2671290 INSTRUCTION (SR0342.8.1)

Attribute	Type	Comment
Text	HTML text	Instruction text to be displayed. **Restriction**: Maximum length is 4000 characters (including HTML tags).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.3.2 GID-2671291 IDENTIFIED EQUIPMENT ENTITY (SR0342.8.2)

Attribute	Type	Comment
Equipment object	Reference	Reference to the output of a preceding phase that provides an identified equipment entity.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.3.3 GID-2671292 MODE (SR0342.8.3)

Attribute	Type	Comment
Mode	Choice list	Defines the processing mode. **Manual completion** (default): Operator confirms the phase. **Automatic completion**: Phase automatically sets the property values and is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.4 Configuration of User-triggered Exceptions

3.3.4.1 GID-2671293 OVERRIDE VALUE DEFINITION (SR0342.8.4)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).** Default setting: **High**, defined by the **DefaultRiskClassForPhaseProcessParameter** configuration key.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 256 characters.

See also **Override value definition (Numeric property bundle) (SR0342.3.1.2)** user-triggered exception (GID-2671811), **Override value definition (String property bundle) (SR0342.3.1.3)** user-triggered exception (GID-2671813), and **Override value definition (Boolean property bundle) (SR0342.3.1.4)** user-triggered exception (GID-2671809).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.4.2 GID-2671294 INPUT AT EQUIPMENT (SR0342.8.5)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**, defined by the **DefaultRiskClassForPhaseProcessParameter** configuration key.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 256 characters.

> See also **Input at equipment (SR0342.3.1.1)** user-triggered exception (GID-2671304).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.5 Boolean Property Bundle

3.3.5.1 BUNDLE PROCESS PARAMETERS (FRAMEWORK CAPABILITY)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2667986).

3.3.5.2 GID-2671296 MASTER (BUNDLE IDENTIFIER) (SR0342.8.8)

Attribute	Type	Comment
Property	String	Equipment property to be written.
Value	Boolean	Value to be set.

Attribute	Type	Comment
Source	Choice list	Defines if the value definition is taken from the process parameter or the equipment entity. Default setting: **Process parameter.**

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.5.3 PROPERTY SELECTION EDITOR (FRAMEWORK CAPABILITY)

The system provides a Property Selection editor for selecting an equipment property based on its data type (numeric, string, boolean). The supported data types depend on the process parameter.

3.3.6 Numeric Property Bundle

3.3.6.1 BUNDLE PROCESS PARAMETERS (FRAMEWORK CAPABILITY)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2667986).

3.3.6.2 GID-2671299 MASTER (BUNDLE IDENTIFIER) (SR0342.8.6)

Attribute	Type	Comment
Property	String	Equipment property to be written.
Low	BigDecimal (Double, Float, Integer)	Value to be set.
Value	BigDecimal (Double, Float, Integer)	Value to be set.
High	BigDecimal (Double, Float, Integer)	Value to be set.

Attribute	Type	Comment
Source	Choice list	Defines if the value definition is taken from the process parameter or the equipment entity. Default setting: **Process parameter**.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.6.3 PROPERTY SELECTION EDITOR (FRAMEWORK CAPABILITY)

The system provides a Property Selection editor for selecting an equipment property based on its data type (numeric, string, boolean). The supported data types depend on the process parameter.

3.3.7 String Property Bundle

3.3.7.1 BUNDLE PROCESS PARAMETERS (FRAMEWORK CAPABILITY)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2667986).

3.3.7.2 GID-2671302 MASTER (BUNDLE IDENTIFIER) (SR0342.8.7)

Attribute	Type	Comment
Property	String	Equipment property to be written.
Value	String	Value to be set.
Source	Choice list	Defines if the value definition is taken from the process parameter or the equipment entity. Default setting: **Process parameter**.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.7.3 PROPERTY SELECTION EDITOR (FRAMEWORK CAPABILITY)

The system provides a Property Selection editor for selecting an equipment property based on its data type (numeric, string, boolean). The supported data types depend on the process parameter.

3.4 Exceptions (SR0342.3+)

The phase supports user-defined, user-triggered (GID-2669461), system-triggered (GID-2669460), and post-completion exceptions (GID-2669462)and their configuration by means of process parameters (GID-2668230).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

3.4.1 System-triggered Exceptions

There are no system-triggered exceptions available.

3.4.2 User-triggered Exceptions (SR0342.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

3.4.2.1 GID-2671304 INPUT AT EQUIPMENT (SR0342.3.1.1)

The **Input at equipment** exception allows an operator to document that property values have been set manually with an interface connected to the physical equipment. With the exception the operator confirms that the values have been set as documented by this phase.

Representation during exception handling:

- Instruction:
  Values set directly at equipment.
  Confirm button.

- Exception text:
  <Exception text>
  (taken from **Input at equipment (SR0342.8.5)** process parameter (GID-2671294))
  Property: <property identifier>

- Example:
  Value was set manually at the HMI.
  Property: AgitatorSpeed

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.2.2 GID-2671305 INPUT AT EQUIPMENT - LOGIC (SR0342.3.1.1.1)

- Trigger: Exception is selected

- Postcondition: Value of property is set

Step	#	Description
Operator confirms exception	10	Phase shows exception description to be signed according to **Input at equipment (SR0342.8.5)** process parameter (GID-2671294).
Operator signs exception	20	Phase records the exception. Additionally, phase adds the exception marker to each cell in the **Automation set** column of the **Active mode (SR0342.1.2)** layout (GID-2671275).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.2.3 BOOLEAN PROPERTY BUNDLE

3.4.2.3.1 GID-2671809 OVERRIDE VALUE DEFINITION (SR0342.3.1.4)

The **Override value definition** exception allows an operator to override the boolean value defined by the process parameter or the entity (see **Boolean property - Master (bundle identifier) (SR0342.8.8)** process parameter (GID-2671296)).

There is one exception per boolean property.
Properties for which an error has been detected are displayed at the top of the list properties.

Representation during exception handling:

- Instruction:
  Override the defined value:
  Current value: <current value from process parameter or entity>
  New value: <available values>
  Confirm button.

- Exception text:
  <Exception text>
  (taken from **Override value definition (SR0342.8.4)** process parameter (GID-2671293))
  Property: <property identifier>
  Old value: <old value>
  New value: <new value>

- Example:
  Value overridden.
  Property: Infrared sensor on
  Old value: True
  New value: False

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.2.3.2 GID-2671810 OVERRIDE VALUE DEFINITION - LOGIC (SR0342.3.1.4.1)

- Trigger: Exception is selected

- Postcondition: Boolean value is set

Step	#	Description
Operator triggers exception	10	Phase displays Exception Window.
	20	Operator selects value.
Operator confirms exception	30	If the following issue occurs, phase displays an error message: ▪ Override value is missing, **No value overridden (SR0342.3.6.12)** error message (GID-2671815). Phase shows exception description to be signed according to **Override value definition (SR0342.8.4)** process parameter (GID-2671293).
Operator signs exception	40	Phase sets the value, resets the "set on automation layer" indicator, and records the exception. Additionally, phase adds the exception marker to the value's cell in the **Active mode (SR0342.1.2)** layout (GID-2671275).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.2.4 NUMERIC PROPERTY BUNDLE

3.4.2.4.1 GID-2671811 OVERRIDE VALUE DEFINITION (SR0342.3.1.2)

The **Override value definition** exception allows an operator to override the numeric value defined by the process parameter or the entity (see **Numeric property - Master (bundle identifier) (SR0342.8.6)** process parameter (GID-2671299)).

There is one exception per numeric property.
Properties for which an error has been detected are displayed at the top of the list properties.

Representation during exception handling:

- Instruction:
  Override the defined value:
  Current values (low, value, high): <current values from process parameter or entity> <UoM>
  New values (low, value, high): <new values> <UoM>
  Confirm button.

- Exception text:
  <Exception text>
  (taken from **Override value definition (SR0342.8.4)** process parameter (GID-2671293))
  Property: <property identifier>
  Old values (low, value, high):
  <value> <UoM>
  <value> <UoM>
  <value> <UoM>
  New values (low, value, high):
  <value> <UoM>
  <value> <UoM>
  <value> <UoM>

  - Example:
    Values overridden.
    Property: AgitatorSpeed
    Old values (low, value, high):
    12.11 rpm
    12.43 rpm
    13.43 rpm
    New values (low, value, high):
    12.61 rpm
    12.93 rpm
    13.93 rpm

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.2.4.2 GID-2671812 OVERRIDE VALUE DEFINITION - LOGIC (SR0342.3.1.2.1)

- Trigger: Exception is selected

- Postcondition: Numeric value is set

Step	#	Description
Operator triggers exception	10	Phase displays Exception Window.
	20	Operator enters values. If the following issue occurs, phase displays an error message: - Data format does not match, **Invalid data format error (SR0342.3.6.9)** error message (GID-2671317).
Operator confirms exception	30	If the following issue occurs, phase displays an error message: - Override value is missing, **No value overridden (SR0342.3.6.10)** error message (GID-2671816). Phase shows exception description to be signed according to **Override value definition (SR0342.8.4)** process parameter (GID-2671293).
Operator signs exception	40	Phase sets the value, resets the "set on automation layer" indicator, and records the exception. Additionally, phase adds the exception marker to the value's cell in the **Active mode (SR0342.1.2)** layout (GID-2671275).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.2.5 STRING PROPERTY BUNDLE

3.4.2.5.1 GID-2671813 OVERRIDE VALUE DEFINITION (SR0342.3.1.3)

The **Override value definition** exception allows an operator to override the string value defined by the process parameter or the entity (see **String property - Master (bundle identifier) (SR0342.8.8)** process parameter (GID-2671296)).

There is one exception per string property.
Properties for which an error has been detected are displayed at the top of the list properties.

Representation during exception handling:

- Instruction:
  Override the defined value:
  Current value: <current value from process parameter or entity>
  New value: <value>
  Confirm button.

- Exception text:
  <Exception text>
  (taken from **Override value definition (SR0342.8.4)** process parameter (GID-2671293))
  Property: <property identifier>
  Old value: <old value>
  New value: <new value>

  - Example:
    Value overridden.
    Property: HeatingPerformed
    Old value: Temperature alarm
    New value: High temperature alarm

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.2.5.2 GID-2671814 Override value definition - Logic (SR0342.3.1.3.1)

- Trigger: Exception is selected

- Postcondition: String value is set

Step	#	Description
Operator triggers exception	10	Phase displays Exception Window.
	20	Operator enters value.
Operator confirms exception	30	If the following issue occurs, phase displays an error message: - Override value is missing, **No value overridden (SR0342.3.6.11)** error message (GID-2671817). Phase shows exception description to be signed according to **Override value definition (SR0342.8.4)** process parameter (GID-2671293).

Step	#	Description
Operator signs exception	40	Phase sets the value, resets the "set on automation layer" indicator, and records the exception. Additionally, phase adds the exception marker to the value's cell in the **Active mode (SR0342.1.2)** layout (GID-2671275).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

3.5 Information Messages

There are no information messages available.

3.6 Questions

There are no questions available.

3.7 Decisions

There are no decisions available.

3.8 Error Messages (SR0342.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

They are composed of up to three levels:

1. header,

2. category, and

3. details (not always used).

The following error messages are available to inform the operator about error conditions.

3.8.1 Set Property-specific Error Messages (Pre-writing)

3.8.1.1 GID-2671309 INVALID CONFIGURATION ERROR (SR0342.3.6.1)

UI text	Comment
▪ The Set action was not successful. ▪ Please set the values directly at the equipment.	▪ Message pack: PhaseEqmAISetOPCValues\<version\> Message ID: CheckBeforeExecuteError_HeaderMsg ▪ Message pack: PhaseEqmAISetOPCValues\<version\> Message ID: IrreparableExecution_ErrorCategory Potential error cause: ▪ Referenced equipment entity is undefined (Null).

The **Details** button provides access to more specific technical information.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.1.2 GID-2671310 INPUT AT EQUIPMENT RECORDED (SR0342.3.6.2)

UI text	Comment
▪ The Set action was not successful. ▪ \<empty string\> ▪ The input at equipment exception has already been recorded.	▪ Message pack: PhaseEqmAISetOPCValues\<version\> Message ID: CheckBeforeExecuteError_HeaderMsg ▪ Message pack: PhaseEqmAISetOPCValues\<version\> Message ID: BusinessLogic_ErrorCategory ▪ Message pack: PhaseEqmAI\<version\> Message ID: WritePrecheck_NoSetAfterInputAtEquipment_ErrorMsg Potential error cause: **Set** button is used after the **Input at equipment (SR0342.3.1.1)** user-triggered exception (GID-2671304) has been signed.

The **Details** button provides access to more specific technical information.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.1.3 GID-2671311 DEFINED VALUES INCOMPLETE (SR0342.3.6.3)

UI text	Comment
▪ The Set action was not successful. ▪ Please define the missing values manually.	▪ Message pack: PhaseEqmAISetOPCValues<version> Message ID: CheckBeforeExecuteError_HeaderMsg ▪ Message pack: PhaseEqmAISetOPCValues<version> Message ID: MissingValues_ErrorCategory Potential error cause: One or more values that should be written are not defined.
▪ The Set action was not successful. ▪ Retry the Set action or set the values directly at the equipment.	▪ Message pack: PhaseEqmAISetOPCValues<version> Message ID: CheckBeforeExecuteError_HeaderMsg ▪ Message pack: PhaseEqmAISetOPCValues<version> Message ID: ReparableExecution_ErrorCategory Potential error cause: Due to a configuration error one or more values could not be written.

The **Details** button provides access to more specific technical information.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.2 Set Property-specific Error Messages (Writing)

3.8.2.1 GID-2671312 SYSTEM ERROR (SR0342.3.6.4)

UI text	Comment
▪ The Set action was not successful. ▪ <empty string>	▪ Message pack: PhaseEqmAISetOPCValues<version> Message ID: ExecutionError_HeaderMsg ▪ Message pack: PhaseEqmAISetOPCValues<version> Message ID: Other_ErrorCategory Potential error cause: ▪ Automation Integration server cannot be reached. ▪ Automation Integration server write failure.

The **Details** button provides access to more specific technical information.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.2.2 GID-2671313 AUTOMATION ERROR (SR0342.3.6.5)

UI text	Comment
▪ The Set action was not successful. ▪ Please set the values directly at the equipment.	▪ Message pack: PhaseEqmAISetOPCValues<version> Message ID: ExecutionError_HeaderMsg ▪ Message pack: PhaseEqmAISetOPCValues<version> Message ID: IrreparableExecution_ErrorCategory Potential error cause: ▪ Tag is enabled but the tag path is undefined. ▪ The property to be written is not defined for the identified equipment entity. ▪ Live Data server write failure.

The **Details** button provides access to more specific technical information.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.2.3 GID-2671314 ERROR MESSAGE GROUPING (SR0342.3.6.6)

If several errors occur during the execution of the Set action, the error messages are combined and displayed in a single error dialog. The three error levels specified in the **Error Messages (SR0342.3.6+)** description (GID-2668235) are used as follows.

The combined error message consists of:

1. One header message,

2. one or more category messages, and

3. one or more detail messages.

UI text	Comment
▪ The Set action was not successful. ▪ <List of category messages>	▪ Message pack: PhaseEqmAISetOPCValues<version> Message ID: ExecutionError_HeaderMsg ▪ Category of **System error (SR0342.3.6.4)** error message (GID-2671312) and/or **Automation error (SR0342.3.6.5)** error message (GID-2671313). Potential error cause: If there are several errors related to the execution of the **Set** button, the displayed error message contains all error categories and details that apply.

The **Details** button provides access to more specific technical information.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.3 *Phase Completion-specific Error Messages*

3.8.3.1 GID-2671315 DEFINED VALUES NOT SET (SR0342.3.6.7)

UI text	Comment
▪ Cannot confirm ▪ Not all values were set successfully at the entity. Retry the Set action or set the values directly at the equipment.	▪ Message pack: PhaseEqmAISetOPCValues<version> Message ID: CompletionError_HeaderMsg ▪ Message pack: PhaseEqmAISetOPCValues<version> Message ID: ReparableConfirm_ErrorCategory Potential error cause: ▪ One or more values that should be written are not defined. ▪ One or more values that should be written cannot be set on the automation layer.

The **Details** button provides access to more specific technical information.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.3.2 GID-2671316 ERROR MESSAGE GROUPING - CONFIRM (SR0342.3.6.8)

If several errors occur when the phase is confirmed, the error messages are combined and displayed in a single error dialog. The three error levels specified in the **Error Messages (SR0342.3.6+)** description link are used as follows.
The combined error message consists of:

1. One header message,

2. one or more category messages, and

3. one or more detail messages.

UI text	Comment
▪ Cannot confirm ▪ <List of category messages>	▪ Message pack: PhaseEqmAISetOPCValues<version> Message ID: CompletionError_HeaderMsg ▪ Category of **System error (SR0342.3.6.4)** error message (GID-2671312)and/or **Automation error (SR0342.3.6.5)** error message (GID-2671313).

UI text	Comment
	Potential error cause: If there are several errors related to phase completion, the displayed error message contains all error categories and details that apply.

The **Details** button provides access to more specific technical information.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.4 User-triggered Exception-specific Error Messages

3.8.4.1 GID-2671317 INVALID DATA FORMAT ERROR (SR0342.3.6.9)

UI text	Comment
▪ Cannot confirm the overridden values. ▪ <empty string> ▪ The value entered for <attribute name> has an unsuitable format. Please enter a value that is valid for the <data type name> data type.	▪ Message pack: PhaseEqmAISetOPCValues<version> Message ID: OverrideExceptionConfirmationError_HeaderMsg ▪ Message pack: PhaseEqmAISetOPCValues<version> Message ID: Other_ErrorCategory ▪ Message pack: PhaseEqmAI<version> Message ID: OverrideInvalidDataFormat_ErrorMsg Potential error cause: The entered text value cannot be converted to a numeric value of the targeted numeric data type.

The **Details** button provides access to more specific technical information.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.4.2 BOOLEAN PROPERTY BUNDLE

3.8.4.2.1 GID-2671815 NO VALUE OVERRIDDEN (SR0342.3.6.12)

UI text	Comment
▪ You have to select a value before you can confirm.	▪ Message pack: PhaseEqmAI<version> Message ID: OverrideBooleanValueNotSet_ErrorMsg Potential error cause: No override value was entered before the user-triggered exception was confirmed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.4.3 NUMERIC PROPERTY BUNDLE

3.8.4.3.1 GID-2671816 NO VALUE OVERRIDDEN (SR0342.3.6.10)

UI text	Comment
▪ Enter an override value.	▪ Message pack: PhaseEqmAI<version> Message ID: OverrideNumericValueNotSet_ErrorMsg Potential error cause: No override value was entered before the user-triggered exception was confirmed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.4.4 STRING PROPERTY BUNDLE

3.8.4.4.1 GID-2671817 NO VALUE OVERRIDDEN (SR0342.3.6.11)

UI text	Comment
▪ You have to enter an override value before you can confirm.	▪ Message pack: PhaseEqmAI<version> Message ID: OverrideStringValueNotSet_ErrorMsg Potential error cause: No override value was entered before the user-triggered exception was confirmed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.9 Output Variables (SR0342.9+)

The following output variables are available to reference the phase's output.

3.9.1 Instance count (Framework capability)

▪ Data type: Long

▪ Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
The count variable of a phase that has not been executed provides 0 as output value.

3.9.2 Start time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the start time of the phase.

3.9.3 Completion time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the completion time of the phase.

3.9.4 Identifier (Framework capability)

- Data type: String

- Usage: The output variable provides the identifier of the phase.

3.9.4.1 GID-2671321 AUTOMATION SET SUCCESSFUL (SR0342.9.1)

- Data type: Boolean

- Values: true, false

- Usage: The output variable states if the set operation on the automation layer was successful.

    - The value is true if all property values have been set.

    - The value is false if at least one of the property values could not be set.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.9.5 Boolean Property Bundle

3.9.5.1 BUNDLE OUTPUT VARIABLE (FRAMEWORK CAPABILITY)

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2667986).

3.9.5.2 GID-2671323 VALUE (SR0342.9.9)

- Data type: Boolean

- Usage: The output variable provides the value of the boolean property tag. The value is Null if N/A is the phase result.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.9.5.3 GID-2671324 AUTOMATION SET SUCCESSFUL (SR0342.9.10)

- Data type: Boolean

- Values: true, false

- Usage: The output variable states if the set operation on the automation layer was successful.

  - The value is true if the property value of the boolean property tag has been set.

  - The value is false if the property values of the boolean property tag could not be set.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.9.6 Numeric Property Bundle

3.9.6.1 BUNDLE OUTPUT VARIABLE (FRAMEWORK CAPABILITY)

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2667986).

3.9.6.2 GID-2671326 VALUE (SR0342.9.2)

- Data type: BigDecimal

- Usage: The output variable provides the actual value of the numeric property tag as a **BigDecimal** value. The value is Null if N/A is the phase result.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.9.6.3 GID-2671327 LOW (SR0342.9.3)

- Data type: BigDecimal

- Usage: The output variable provides the value of the numeric property tag as a **BigDecimal** value. The value is Null if N/A is the phase result.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.9.6.4 GID-2671328 HIGH (SR0342.9.4)

- Data type: BigDecimal

- Usage: The output variable provides the value of the numeric property tag as a **BigDecimal** value. The value is Null if N/A is the phase result.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.9.6.5 GID-2671329 UNIT OF MEASURE (SR0342.9.5)

- Data type: String

- Usage: The output variable provides the unit of measure of the numeric property tag. The value is Null if N/A is the phase result.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.9.6.6 GID-2671330 AUTOMATION SET SUCCESSFUL (SR0342.9.6)

- Data type: Boolean

- Values: true, false

- Usage: The output variable states if the set operation on the automation layer was successful.

  - The value is true if all property values of the numeric property tag have been set.

  - The value is false if at least one of the property values of the numeric property tag could not be set.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.9.7 *String Property Bundle*

3.9.7.1 BUNDLE OUTPUT VARIABLE (FRAMEWORK CAPABILITY)

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2667986).

3.9.7.2 GID-2671332 VALUE (SR0342.9.7)

- Data type: String

- Usage: The output variable provides the value of the string property tag. The value is Null if N/A is the phase result.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.9.7.3 GID-2671333 AUTOMATION SET SUCCESSFUL (SR0342.9.8)

- Data type: Boolean

- Values: true, false

- Usage: The output variable states if the set operation on the automation layer was successful.

  - The value is true if the property value of the string property tag has been set.

  - The value is false if the property values of the string property tag could not be set.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.10 Performance (SR0342.12+)

3.10.1 *GID-2669474 Performance of Set Activity (SR0342.12.1)*

The time for setting the OPC values on the automation layer does not take longer than 5 seconds. Any potential delay by the OPC server or the PLC communication is not considered.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

4 Monitor Numeric Value Phase (SR0360+)

The **Monitor numeric value** phase reads a numeric value within a defined monitoring period and compares the value with a pre-defined condition.

An example use case is:

- Waiting for a specific numeric value to reach a certain value before processing can continue
  An agitator needs several minutes to reach the speed set-point of 50 rpm. The phase evaluates the speed value every 5 seconds and if 50 rpm is reached within a pre-defined monitoring period, the agitator is ready for use.

- Assuring that a specific numeric value does not exceed a pre-defined limit
  Within a given monitoring period of 30 minutes, the phase evaluates the temperature every 10 seconds. If the temperature exceeds 30 °C, an exception is recorded.

Different phase modes enable the usage in various situations that can occur during processing:

- In the **Manual completion** mode, the operator manually completes the phase.

- In the **Automatic completion** mode, under certain conditions, the phase is automatically completed without any operator interaction.

The affected equipment entity, monitoring period, condition string, and the timestamp when the condition is met are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2669477).

The condition will be considered to be met if the value matches its requirements and the corresponding tag quality is **Good**.

Both the monitoring period and the tag update rate are configurable; the tag update rate in Data Manager on equipment property level, the monitoring period in Recipe and Workflow Designer on process parameter level.

> **TIP**
> - Changes of a value that fulfill the condition only temporarily between two read-cycles are not detected.
> - Due to technical reasons, the accuracy of the **Double** or **Float** numeric data type cannot be guaranteed. Hence, the result of the **Value == 13.4** condition can be unexpected if the value is of the **Double** or **Float** numeric data type.

Anomalies that occur during processing are covered by the phase exception handling (GID-2668241)(e.g. condition not fulfilled within monitor period).

After completion the phase displays the affected equipment entity, condition string, monitor duration and the phase result in the Execution Window.

The Navigator displays the identifier of the affected equipment entity.

Run process until required layer thickness has been reached.

Entity: Coater_AM / Automated
Condition: Layer Thickness >= 80 (Good)
Duration: 8min (until 10/07/2022 12:22:01 PM CEST)

Result:
Value: Confirm ▨

Figure 3: Monitor numeric value during execution

4.1 Layout

The phase provides individual layouts for its representation during execution (GID-2669475), in the Navigator (GID-2669476)and in the sub-report (GID-2669477).

4.1.1 *Representation during Execution (SR0360.1+)*

The representation during execution depends on the phase mode.

4.1.1.1 GID-2671334 PREVIEW MODE (SR0360.1.1)

1. <Instruction text>
   (taken from **Instruction (SR0360.8.1)** process parameter (GID-2671346))

2. Equipment entity:
   Condition: [<value> <comparator>] <property identifier> <comparator> <value> (<meaning of "condition met">)
   Duration: <d hh mm ss>
   (taken from **Numeric property (SR0360.8.4)** process parameter (GID-2671349))
   Result:
   Value:

3. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

4.1.1.2 GID-2671335 ACTIVE MODE (SR0360.1.2)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0360.8.1)** process parameter (GID-2671346))

3. Equipment entity: <equipment entity identifier>/<equipment entity short description>
   (taken from **Identified equipment entity (SR0360.8.2)** process parameter (GID-2671347))
   Condition: [<value> <comparator>] <property identifier> <comparator> <value> (<meaning of "condition met">)
   Duration: <d hh mm ss> (until end time <end time>)
   (taken from **Numeric property (SR0360.8.4)** process parameter (GID-2671349))
   Result: **Condition met** or **Condition not met**
   Value: <value> <UoM> (<tag timestamp> or **N/A** or **Manual**)

   ▪ Tag timestamp: when value was retrieved from equipment e.g. 02/22/2013 12:49:09 PM CET

   ▪ Manual in case a value has been overridden by using the **Stop monitoring and record result (SR0360.3.1.1)** user-triggered exception link.

4. For the representation, see **Monitor a numeric value (SR0360.2.1)** function (GID-2669478).

5. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.1.1.3 GID-2671336 COMPLETED MODE (SR0360.1.3)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0360.8.1)** process parameter (GID-2671346))

3. Equipment entity: <equipment entity identifier>/<equipment entity short description>
   (taken from **Identified equipment entity (SR0360.8.2)** process parameter (GID-2671347))
   Condition: [<value> <comparator>] <property identifier> <comparator> <value> (<meaning of "condition met">)
   Duration: <d hh mm ss>
   (taken from **Numeric property (SR0360.8.4)** process parameter (GID-2671349))
   Result: **Condition met** or **Condition not met**
   Value: **<value> <UoM>** (**<tag timestamp>** or **N/A** or **Manual**)

   ▪ Tag timestamp: when value was retrieved from equipment e.g. 02/22/2013 12:49:09 PM CET

   ▪ Manual: in case a value has been overridden by using the **Stop monitoring and record result (SR0360.3.1.1)** user-triggered exception link.

4. For the representation, see **Monitor a numeric value (SR0360.2.1)** function (GID-2671335).

5. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.1.2 Representation in Navigator (SR0360.4+)

The Navigator provides the following details:

4.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>

  - Example:
    Monitor mixer value

4.1.2.2 GID-2671338 INFORMATION COLUMN (SR0360.4.1)

- <Identifier of affected equipment entity>

  - Example: MixerA12

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

4.1.2.3 ACTION COLUMN

- There are no actions available.

4.1.3 Representation in Sub-report (SR0360.5+)

The sub-report contains the following information:

4.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>

- <Completion time>

- <Unit procedure> / <operation> / <phase>

- <Work center> / <station> / <device> - <phase completion user>

4.1.3.2 GID-2671341 SUB-REPORT ELEMENTS (SR0360.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)

- Instruction text

- Entity (identifier and short description)

- Duration

- Condition string ([<value>] <comparator> <value> <meaning of "condition met">)

- Result

- Value

- Timestamp of tag value

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2 Business Logic (SR0360.2+)

The phase implements the following business logic.

4.2.1 GID-2669478 Monitor a numeric value (SR0360.2.1)

- Function: Monitor a numeric value of affected equipment entity and property

- Trigger: Phase becomes active

- Postcondition: Monitoring is completed

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0360.1.2)** layout (GID-2671335). If monitoring could not be activated, phase displays **Automation error (SR0360.3.6.1)** error message (GID-2669488).
Phase monitors value	20	Within the defined period (**Numeric property (SR0360.8.4)** process parameter (GID-2671349)), phase monitors the numeric value and updates phase representation. As long as the value is monitored, phase displays end time to the right of the duration. Monitoring is terminated when - condition is fulfilled (see step 30) or - monitoring duration has expired (see step 40).

Step	#	Description
Phase behavior when condition is fulfilled	30	Values are only evaluated against the pre-defined condition if the tag quality is **Good**. Bad quality tags are not evaluated. ■ Phase displays the result as **Condition met**. Phase displays the read value and its timestamp. ■ If **Mode (SR0360.8.3)** process parameter (GID-2671348) is set to **Automatic completion** and **Meaning of "condition met"** attribute of **Numeric property (SR0360.8.4)** process parameter (GID-2671349) is set to **Good**, phase is completed. ■ If **Meaning of "condition met"** of **Numeric property (SR0360.8.4)** process parameter (GID-2671349) is set to **Exception**: Phase creates **Monitoring exception (SR0360.3.2.1)** system-triggered exception (GID-2671354) and must be completed manually.
Phase behavior when monitoring duration has expired	40	■ Phase displays the result as **Condition not met**. Phase displays the values as **N/A** with **N/A** as timestamp. ■ If **Meaning of "condition met"** attribute of **Numeric property (SR0360.8.4)** process parameter (GID-2671349) is set to **Good**: Phase creates **Monitoring exception (SR0360.3.2.1)** system-triggered exception (GID-2671354) and must be completed manually. ■ If **Mode (SR0360.8.3)** process parameter (GID-2671348) is set to **Automatic completion** and **Meaning of "condition met"** attribute of **Numeric property (SR0360.8.4)** process parameter (GID-2671349) is set to **Exception**, phase is completed.
Operator confirms phase	50	■ If monitoring is active, phase displays **Monitoring in progress (SR0360.3.6.2)** error message (GID-2669489). In this case, the **Stop monitoring and record result (SR0360.3.1.1)** user-triggered exception (GID-2671358) needs to be recorded before the phase can be completed. ■ If a system-triggered exception has been raised before, it needs to be recorded before the phase can be completed. ■ Otherwise, phase is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3 Process Parameters (SR0360.8+)

The following process parameters define the behavior of the phase.

4.3.1 Instruction Table-specific Parameters

4.3.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

4.3.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. **Restriction**: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

4.3.2 Instruction Link-specific Parameters

4.3.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Instruction text	HTML text	Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2671345). Example: Refer to {SOP1270} for guidance. Maximum length is 2000 characters (including HTML tags).

4.3.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

4.3.3 Basic Parameters

4.3.3.1 GID-2671346 INSTRUCTION (SR0360.8.1)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed. **Restriction**: Maximum length is 4000 characters (including HTML tags).
Column 2	HTML text	Not used.
Column 3	HTML text	

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.3.2 GID-2671347 IDENTIFIED EQUIPMENT ENTITY (SR0360.8.2)

Attribute	Type	Comment
Equipment object	Reference	Reference to the output of a preceding phase that provides an identified equipment entity.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.3.3 GID-2671348 MODE (SR0360.8.3)

Attribute	Type	Comment
Mode	Choice list	Defines the processing mode. **Manual completion** (default): Operator confirms the phase. **Automatic completion**: Phase automatically gets the property value and is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.4 Property Type Parameters

4.3.4.1 GID-2671349 NUMERIC PROPERTY (SR0360.8.4)

Attribute	Type	Comment
Property	String	Equipment property to be read.
Comparator	Choice list	Defines the comparison, where **x** is the monitored value. **x == value1**: equal to **x != value1**: not equal to **x < value1**: less than **x <= value 1**: less than or equal to **x >= value1**: greater than or equal to **x > value1**: greater than **value1 <= x <= value2**: closed interval **value1 < x < value2**: open interval Default setting: **x >= value1**
Value1	BigDecimal	Defines the first value of the comparison.
Value2	BigDecimal	Defines the second value of the comparison, if applicable.
Meaning of "condition met"	Choice list	Defines the string to be displayed as result of the comparison. Available settings: **Good**, **Exception**. Default setting: **Good**
Monitor duration	Duration	Defines the monitoring period in hh:mm:ss. The minimum duration is one second. Specified milliseconds are not displayed in the phase user interface. **Note**: The duration must always be longer than the tag update rate that is configured on equipment property level.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.4.2 PROPERTY SELECTION EDITOR (FRAMEWORK CAPABILITY)

The system provides a Property Selection editor for selecting an equipment property based on its data type (numeric, string, boolean). The supported data types depend on the process parameter.

4.3.5 Configuration of System-triggered Exceptions

4.3.5.1 GID-2671351 MONITORING EXCEPTION (SR0360.8.5)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).** Default setting: **High.**
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

> See also **Monitoring exception (SR0360.3.2.1)** system-triggered exception (GID-2671354).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.5.2 GID-2671352 UNFORESEEN RESUME (SR0360.8.7)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).** Default setting: **High.**

Attribute	Type	Comment
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Unforeseen resume (SR0360.3.2.2)** system-triggered exception (GID-2669478).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.6 Configuration of User-triggered Exceptions

4.3.6.1 GID-2671353 STOP MONITORING AND RECORD RESULT (SR0360.8.6)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Stop monitoring and record result (SR0360.3.1.1)** user-triggered exception (GID-2671358).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.4 Exceptions (SR0360.3+)

The phase supports user-defined, user-triggered (GID-2669486), system-triggered (GID-2669485), and post-completion exceptions (GID-2669487)and their configuration by means of process parameters (GID-2668240).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

4.4.1 System-triggered Exceptions (SR0360.3.2+)

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

4.4.1.1 GID-2671354 MONITORING EXCEPTION (SR0360.3.2.1)

The exception text is extended by messages specific to the current situation.

Representation of the exception:

- <Exception text>
  (taken from **Monitoring exception (SR0360.8.5)** process parameter (GID-2671351))

  - Condition <property identifier> <comparator> <value> (<meaning of exception>) met by [<monitoring result value> | N/A]

  - Condition <property identifier> <comparator> <value> (<meaning of exception>) not met by [<monitoring result value> | N/A]

  - Example:
    Monitoring exception occurred:
    Condition Speed >= 50 rpm (Good) met by 51.4 rpm

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.4.1.2 GID-2671355 MONITORING EXCEPTION - LOGIC (SR0360.3.2.1.1)

Trigger: Either the condition is fulfilled and defined as **Exception** or the condition is defined as **Good** and the monitor duration has expired.
For the settings, see **Comparator**, **Meaning of "condition met"**, and **Monitor duration** attributes of the **Numeric property (SR0360.8.4)** process parameter (GID-2671349).

Postcondition: Exception is recorded

Step	#	Description
Operator triggers exception	10	Phase records the exception.
	20	Phase returns to **Active mode (SR0360.1.2)** layout (GID-2671335).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.4.1.3 GID-2671356 UNFORESEEN RESUME (SR0360.3.2.2)

Representation of the exception:

- <Exception text>
  (taken from **Unforeseen resume (SR0360.8.7)** process parameter (GID-2671352))
  The system has been resumed while monitoring a numeric value of <property identifier>. It must be ensured that the data recorded so far matches the physical situation on the shop floor.
  Consider to stop monitoring and record an exception with the monitoring result.

  - Example:
    A critical resume situation has occurred. Contact your supervisor before proceeding.
    The system has been resumed while monitoring a numeric value of speed. It must be ensured that the data recorded so far matches the physical situation on the shop floor.
    Consider to stop monitoring and record an exception with the monitoring result.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.4.1.4 GID-2671357 UNFORESEEN RESUME – LOGIC (SR0360.3.2.2.1)

Trigger: Monitoring a numeric value has been interrupted while the phase was active so that the system needs to be resumed

Postcondition: Phase is back in active mode

Step	#	Description
Phase activation	10	Phase displays the **Unforeseen resume (SR0360.3.2.2)** system-triggered exception.

Step	#	Description
Operator triggers exception	20	Phase records the exception.
	30	Phase restarts monitoring again with the full monitor duration configured (taken from **Numeric property (SR0360.8.4)** process parameter (GID-2671349)).
	40	Phase returns to **Active mode (SR0365.1.2)** layout (GID-2671361).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.4.2 User-triggered Exceptions (SR0360.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

4.4.2.1 GID-2671358 STOP MONITORING AND RECORD RESULT (SR0360.3.1.1)

The **Stop monitoring and record result** exception allows an operator to terminate monitoring before the monitoring duration has expired and to record the monitoring result value manually.

The exception is only enabled if monitoring is active.

Representation during exception handling:

- Instruction:
  Stop and record the monitoring value of <property identifier>
  Value: <value><UoM>
  Confirm button.

- Exception text:
  <Exception text>
  (taken from **Stop monitoring and record result (SR0360.8.6)** process parameter (GID-2671353))
  Property: <property identifier>
  Recorded value: <value> <UoM>

  - Example:
    Monitoring stopped manually.
    Property: temperature
    Recorded value: 33 °C

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.4.2.2 GID-2671359 STOP MONITORING - LOGIC (SR0360.3.1.1.1)

- Trigger: Exception is selected

- Postcondition: Monitoring of numeric value is stopped and value is recorded

Step	#	Description
Operator triggers exception	10	Phase shows exception description to be signed according to **Stop monitoring and record result (SR0360.8.6)** process parameter (GID-2671353).
Operator provides value	20	If the following issue occurs, phase displays an error message: ■ Value is entered and data format does not match, **Invalid data format error (SR0360.3.6.3)** error message (GID-2669490).
Operator signs exception	30	Phase records the exception.
Phase activation	40	Phase returns to the **Active mode (SR0360.1.2)** layout (GID-2671335).
Phase behavior when a value is provided	50	Phase evaluates the condition and displays the result correspondingly: **Condition met** or **Condition not met**. ■ If **Meaning of "condition met"** attribute of **Numeric property (SR0360.8.4)** process parameter (GID-2671349)is set to **Good**: Phase displays the entered value and **N/A** as timestamp. If **Mode (SR0360.8.3)** process parameter link is set to **Automatic completion**, phase is completed. ■ If **Meaning of "condition met"** of **Numeric property (SR0360.8.4)** process parameter (GID-2671349)is set to **Exception**: Phase displays the entered value and **Manual** as timestamp. Phase creates **Monitoring exception (SR0360.3.2.1)** system-triggered exception (GID-2671354)and must be completed manually.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

4.5 Information Messages

There are no information messages available.

4.6 Questions

There are no questions available.

4.7 Decisions

There are no decisions available.

4.8 Error Messages (SR0360.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

4.8.1 GID-2669488 Automation error (SR0360.3.6.1)

UI text	Comment
Cannot monitor the value of the <property identifier> property. Please verify your system configuration and try again or override. System errors: <automation-related message>.	Message pack: EQAIMonNumeric<version> Message ID: AutomationErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.8.2 GID-2669489 Monitoring in progress (SR0360.3.6.2)

UI text	Comment
Cannot confirm, since monitoring is in progress.	Message pack: EQAIMonNumeric<version> Message ID: CannotComplete_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.8.3 GID-2669490 Invalid data format error (SR0360.3.6.3)

UI text	Comment
▪ Cannot confirm the overridden values. ▪ <empty string> ▪ The value entered for <attribute name> has an unsuitable format. Please enter a value that is valid for the <data type name> data type.	▪ Message pack: PhaseEqmAISetManager<version> Message ID: OverrideExceptionConfirmationError_HeaderMsg ▪ Message pack: PhaseEqmAISetManager<version> Message ID: Other_ErrorCategory ▪ Message pack: PhaseEqmAI<version> Message ID: OverrideInvalidDataFormat_ErrorMsg Potential error cause: The entered text value cannot be converted to a numeric value of the targeted numeric data type.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.9 Output Variables (SR0360.9+)

The following output variables are available to reference the phase's output.

4.9.1 Instance count (Framework capability)

▪ Data type: Long

▪ Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
The count variable of a phase that has not been executed provides 0 as output value.

4.9.2 Start time (Framework capability)

▪ Data type: Timestamp

▪ Usage: The output variable provides the start time of the phase.

4.9.3 Completion time (Framework capability)

▪ Data type: Timestamp

▪ Usage: The output variable provides the completion time of the phase.

4.9.4 Identifier (Framework capability)

▪ Data type: String

▪ Usage: The output variable provides the identifier of the phase.

4.9.5 GID-2669495 Monitoring exception occurred (SR0360.9.1)

- Data type: Boolean

- Values: true, false

- Usage: The output variable states if an exception has occurred while the phase was active.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.9.6 GID-2669496 Value (SR0360.9.3)

- Data type: MeasuredValue

- Usage: The output variable provides the value and its unit of measure as a **MeasuredValue** object. The value is Null if N/A is the phase result.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.9.7 GID-2669497 Timestamp of tag (SR0360.9.2)

- Data type: Timestamp

- Usage: The output variable provides the timestamp when the value was read.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5   Get Alarms Phase (SR0365+)

The **Get alarms** phase polls alarm tags within a defined interval of a single equipment entity on the automation layer.

An example use case is:

- Recording alarms and follow-up actions
  The status of alarm tags is polled every five seconds. In case an alarm has occurred, the alarm itself is documented and, according to the recipe design, related follow-up actions can be executed before the **Get alarms** phase is activated again.

The phase supports up to 20 alarm tags.
The tag quality is not evaluated while determining if an alarm or error condition has been reached.

Different phase modes enable the usage in various situations that can occur during processing:

- In the **Manual completion** mode, the operator manually completes the phase.

- In the **Automatic completion** mode, under certain conditions, the phase is automatically completed without any operator interaction.

The affected equipment entity, the affected alarm property, its alarm identifier, statuses, and timestamps are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2669500).

Anomalies that occur during processing are covered by the phase exception handling (GID-2668250)(e.g. tag cannot be read).

The list of occurred alarms is available as phase output. Depending on the recipe design, this list of alarms can be evaluated within a transition condition in order to control related follow-up production steps.

After completion the phase displays the affected alarm property, its tags, and their statuses in the Execution Window.

The Navigator displays the identifier of the affected equipment entity.

Figure 4: Get alarms during execution

5.1 Layout

The phase provides individual layouts for its representation during execution (GID-2669498), in the Navigator (GID-2669499), and in the sub-report (GID-2669500).

5.1.1 Representation during Execution (SR0365.1+)

The representation during execution depends on the phase mode.

5.1.1.1 GID-2671360 PREVIEW MODE (SR0365.1.1)

1. <Instruction text>
   (taken from **Instruction (SR0365.8.1)** process parameter (GID-2671371))

2. Entity:
   Property: <property identifier> / <property short description>
   (taken from **Alarm property (SR0365.8.4)** process parameter (GID-2671374))

3. Status: N/A

4. List of alarms (with status and identifier)
   (taken from **Alarm property (SR0365.8.4)** process parameter (GID-2671374))

5. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

5.1.1.2 GID-2671361 ACTIVE MODE (SR0365.1.2)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0365.8.1)** process parameter (GID-2671371))

3. Entity: <equipment entity identifier>/<equipment entity short description>
   (taken from **Identified equipment entity (SR0365.8.2)** process parameter (GID-2671372))
   Property: <property identifier> / <property short description>
   (taken from **Alarm property (SR0365.8.4)** process parameter (GID-2671374))

4. Status: <status of tag reading>

   ▪ If reading has been stopped: Stopped at <timestamp>

   ▪ If reading is ongoing: Update every: <hh:mm:ss> / Next update: <timestamp>
     (taken from **Alarm property (SR0365.8.4)** process parameter (GID-2671374))

5. Overall status <icon>

   ▪ Checkmark, if no alarm has been raised, no error has occurred, and all tags have been read successfully.

   ▪ Alarm symbol, if at least one alarm has been raised, regardless of the statuses of all other tags.

   ▪ Error symbol, if at least one error has occurred and no alarms have been raised, regardless of whether all other alarm tags have been read successfully.

6. List of alarms (with status and identifier)
   (taken from **Alarm property (SR0365.8.4)** process parameter (GID-2671374))

   ▪ Checkmark

   ▪ Alarm symbol

   ▪ Error symbol

7. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.1.1.3 GID-2671362 COMPLETED MODE (SR0365.1.3)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0365.8.1)** process parameter (GID-2671371))

3. Entity: <equipment entity identifier>/<equipment entity short description>
   (taken from **Identified equipment entity (SR0365.8.2)** process parameter (GID-2671372))
   Property: <property identifier> / <property short description>
   (taken from **Alarm property (SR0365.8.4)** process parameter (GID-2671374))

4. Status: Stopped at <timestamp>

5. Overall status <icon>

   - Checkmark, if no alarm has been raised, no error has occurred, and all tags have been read successfully.

   - Alarm symbol, if at least one alarm has been raised, regardless of the statuses of all other tags.

   - Error symbol, if at least one error has occurred and no alarms have been raised, regardless of whether all other alarm tags have been read successfully.

6. List of alarms (with status and identifier)
   (taken from **Alarm property (SR0365.8.4)** process parameter (GID-2671374))

   - Checkmark

   - Alarm symbol

   - Error symbol

7. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.1.2 Representation in Navigator (SR0365.4+)

The Navigator provides the following details:

5.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

   - <Phase name>

      - Example:
        Get mixer alarms

5.1.2.2 GID-2671364 INFORMATION COLUMN (SR0365.4.1)

   - <Identifier of affected equipment entity>

      - Example: MixerA12

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

5.1.2.3 ACTION COLUMN

   - There are no actions available.

5.1.3 Representation in Sub-report (SR0365.5+)

The sub-report contains the following information:

5.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>

- <Completion time>

- <Unit procedure> / <operation> / <phase>

- <Work center> / <station> / <device> - <phase completion user>

5.1.3.2 GID-3077449 SUB-REPORT ELEMENTS (SR0365.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)

- Instruction text

- Entity (identifier and short description)

- Alarm property (identifier and short description)

- Overall status

- List of alarms

    - Identifier

    - Status (Good, Alarm, Error)

    - Timestamp

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2 Business Logic (SR0365.2+)

The phase implements the following business logic.

5.2.1 GID-2669501 Check for alarms (SR0365.2.1)

- Function: Check for alarms of affected equipment entity and property

- Trigger: Phase becomes active

- Postcondition: Check for alarms is completed

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0365.1.2)** layout link. If the alarm check cannot be started and **Enabled** attribute of **Alarm exception (SR0365.8.5)** process parameter (GID-2671376)is set to **Yes**, phase displays **Invalid property configuration error (SR0365.3.6.2)** error message (GID-2669658)or **Invalid entity configuration error (SR0365.3.6.3)** error message (GID-2669659).
Phase polls tags	20	Within the defined interval (**Alarm property (SR0365.8.4)** process parameter (GID-2671374)), phase polls alarms tags for their status and updates phase representation. Polling is terminated when ▪ at least one alarm is raised (see step 30), ▪ at least one error has occurred, or ▪ the operator confirms the phase (see step 50).
Phase behavior when at least one alarm or one error is raised	30	▪ **Enabled** attribute of **Alarm exception (SR0365.8.5)** process parameter link is set to **Yes**: Phase creates **Alarm exception (SR0365.3.2.1)** system-triggered exception (GID-2671378)and must be completed manually. ▪ **Enabled** attribute of **Alarm exception (SR0365.8.5)** process parameter (GID-2671376)is set to **No**: Phase checks setting of **Mode (SR0365.8.3)** process parameter link (see step 40).
Phase checks setting of **Mode (SR0365.8.3)** process parameter (GID-2671373)	40	▪ Mode is set to **Manual completion**: Phase stops checking for alarms. ▪ Mode is set to **Automatic completion**: Phase stops checking for alarms and is completed.
Operator confirms phase	50	▪ Phase checks for not yet recorded **Alarm exception (SR0365.3.2.1)** system-triggered exceptions (GID-2671378). If no exception has been recorded, at least one alarm is raised, and **Enabled** attribute of **Alarm exception (SR0365.8.5)** process parameter link is set to **Yes**, phase creates **Alarm exception (SR0365.3.2.1)** system-triggered exception (GID-2671378)again. ▪ Phase is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3 Process Parameters (SR0365.8+)

The following process parameters define the behavior of the phase.

5.3.1 Instruction Table-specific Parameters

5.3.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

5.3.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. **Restriction**: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

5.3.2 Instruction Link-specific Parameters

5.3.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Instruction text	HTML text	Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2671370). Example: Refer to {SOP1270} for guidance. Maximum length is 2000 characters (including HTML tags).

5.3.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

5.3.3 Basic Parameters

5.3.3.1 GID-2671371 INSTRUCTION (SR0365.8.1)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed. **Restriction**: Maximum length is 4000 characters (including HTML tags).
Column 2	HTML text	Not used.
Column 3	HTML text	

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.3.2 GID-2671372 IDENTIFIED EQUIPMENT ENTITY (SR0365.8.2)

Attribute	Type	Comment
Equipment object	Reference	Reference to the output of a preceding phase that provides an identified equipment entity.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.3.3 GID-2671373 MODE (SR0365.8.3)

Attribute	Type	Comment
Mode	Choice list	Defines the processing mode. **Manual completion** (default): Operator confirms the phase. **Automatic completion**: Phase automatically gets the property value and is completed. In this mode, avoid infinite looping by properly resetting alarms before re-entering the phase.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.4 Property Type Parameters

5.3.4.1 GID-2671374 ALARM PROPERTY (SR0365.8.4)

Attribute	Type	Comment
Property	String	Equipment property to be read. Supported property data type: FlexibleTagDefinition with tags of boolean Live Data type.
Update interval	Duration	Defines the interval in hh:mm:ss between read operations. The minimum interval is set to 1 second if the interval is not defined at all or configured to be less than that.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.4.2 PROPERTY SELECTION EDITOR (FRAMEWORK CAPABILITY)

The system provides a Property Selection editor for selecting an equipment property based on its data type (numeric, string, boolean). The supported data types depend on the process parameter.

5.3.5 Configuration of System-triggered Exceptions

5.3.5.1 GID-2671376 ALARM EXCEPTION (SR0365.8.5)

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, the phase creates a system-triggered exception when an alarm is raised or an error occurred and alarms cannot be retrieved. Default setting: **Yes**.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.

Attribute	Type	Comment
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Alarm exception (SR0365.3.2.1)** system-triggered exception (GID-2671378).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.5.2 GID-2671377 UNFORESEEN RESUME (SR0365.8.6)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).** Default setting: **High.**
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Unforeseen resume (SR0365.3.2.2)** system-triggered exception (GID-2671380).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.4 Exceptions (SR0365.3+)

The phase supports user-defined, user-triggered (GID-2669508), system-triggered (GID-2669507), and post-completion exceptions (GID-2669509)and their configuration by means of process parameters (GID-2668249).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

5.4.1 System-triggered Exceptions (SR0365.3.2+)

A system-triggered exception is represented in a message dialog along with an Exception button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available:

5.4.1.1 GID-2671378 ALARM EXCEPTION (SR0365.3.2.1)

Representation of the exception:

- \<Exception text\>
  (taken from **Alarm exception (SR0365.8.5)** process parameter (GID-2671376))
  The exception text is extended by additional information specific to the exception case:

  - Alarms and errors:
    Received: \<alarm identifier 1\>; \<alarm identifier 2\>
    Not readable: \<alarm identifier 3, non-boolean\>;\<alarm identifier 4, non-boolean\>

  - Alarms:
    Received: \<alarm identifier 1\>; \<alarm identifier 2\>

  - Errors:
    Not readable: \<alarm identifier 3, non-boolean\>;\<alarm identifier 4, non-boolean\>

  - Example:
    Alarm exception occurred:
    Received: AlarmTagSensor1; AlarmTagLidOpen13
    Not readable: AlarmTagVessels17

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.1.2 GID-2671379 ALARM EXCEPTION - LOGIC (SR0365.3.2.1.1)

- Trigger: At least one alarm has been raised or one error has occurred

- Postcondition: Exception is recorded

Step	#	Description
System triggers exception	10	Phase records the exception.
	20	Phase returns to **Active mode (SR0365.1.2)** layout (GID-2671361).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.1.3 GID-2671380 UNFORESEEN RESUME (SR0365.3.2.2)

Representation of the exception:

- <Exception text>
  (taken from **Unforeseen resume (SR0365.8.6)** process parameter (GID-2671377))
  The system has been resumed while monitoring <property identifier>. It must be ensured that the data recorded so far matches the physical situation on the shop floor.
  Consider to stop monitoring.

  - Example:
    A critical resume situation has occurred. Contact your supervisor before proceeding.
    The system has been resumed while monitoring AlarmsTagsMixer. It must be ensured that the data recorded so far matches the physical situation on the shop floor.
    Consider to stop monitoring.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.1.4 GID-2671381 UNFORESEEN RESUME - LOGIC (SR0365.3.2.2.1)

- Trigger: Monitoring alarms has been interrupted while the phase was active so that the system needs to be resumed

- Postcondition: Phase is back in active mode and alarm monitoring is restarted

Step	#	Description
Phase activation	10	Phase displays the **Unforeseen resume (SR0365.3.2.2)** system-triggered exception (GID-2671380).

Step	#	Description
Operator triggers exception	20	Phase records the exception.
	30	Phase returns to **Active mode (SR0365.1.2)** layout (GID-2671361).
	40	Phase restarts alarm monitoring.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.2 User-triggered Exceptions

There are no user-triggered exceptions available.

5.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

5.5 Information Messages

There are no information messages available.

5.6 Questions

There are no questions available.

5.7 Decisions

There are no decisions available.

5.8 Error Messages (SR0365.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

They are composed of up to three levels:

1. header,

2. category, and

3. details (not always used).

The following error messages are available to inform the operator about error conditions.

5.8.1 GID-2669657 Value retrieval in progress (SR0365.3.6.1)

UI text	Comment
▪ Cannot confirm. Please wait while the values are being retrieved.	▪ Message pack: PhaseEqmAIGetAlarms<version> Message ID: alarmStatusNotSet_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.8.2 GID-2669658 Invalid property configuration error (SR0365.3.6.2)

UI text	Comment
▪ Cannot start the alert monitoring. ▪ <empty string> ▪ The <entity identifier> entity does not have a <property identifier> property.	▪ Message pack: PhaseEqmAIGetAlarms<version> Message ID: CheckBeforeExecuteError_HeaderMsg ▪ Message pack: PhaseEqmAIGetAlarms<version> Message ID: IrreparableExecution_ErrorCategory ▪ Message pack: PhaseEqmAI<version> Message ID: PropertyNotFulfilled_ErrorMsg Potential error cause: ▪ The property to be read is not defined for the identified equipment entity.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.8.3 GID-2669659 Invalid entity configuration error (SR0365.3.6.3)

UI text	Comment
▪ Cannot start the alert monitoring. ▪ <empty string> ▪ Cannot find the expected entity.	▪ Message pack: PhaseEqmAIGetAlarms<version> Message ID: CheckBeforeExecuteError_HeaderMsg ▪ Message pack: PhaseEqmAIGetAlarms<version> Message ID: IrreparableExecution_ErrorCategory ▪ Message pack: PhaseEqmAI<version> Message ID: IdentifiedEquipmentNull_ErrorMsg

UI text	Comment
	Potential error cause: ▪ The equipment entity to be used cannot be found. Potentially the recipe parameter is not defined.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.9 Output Variables (SR0365.9+)

The following output variables are available to reference the phase's output.

5.9.1 Instance count (Framework capability)

- Data type: Long

- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
The count variable of a phase that has not been executed provides 0 as output value.

5.9.2 Start time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the start time of the phase.

5.9.3 Completion time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the completion time of the phase.

5.9.4 Identifier (Framework capability)

- Data type: String

- Usage: The output variable provides the identifier of the phase.

5.9.5 GID-2669664 Alarm tags (SR0365.9.1)

- Data type: String

- Usage: The output variable provides a semicolon-separated list of the tag identifiers for which an alarm has been set. The list is empty if no alarm has occurred.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.9.6 GID-2669665 Overall status (SR0365.9.2)

- Data type: String

- Values: GOOD, ALARM, ERROR

- Usage: The output variable provides the overall status of the alarm tags.

  - The value is GOOD if no alarm has been raised, no error has occurred, and all tags have been read successfully.

  - The value is ALARM if at least one alarm has been raised, regardless of the statuses of all other tags.

  - The value is ERROR if at least one error has occurred and no alarms have been raised, regardless of whether all other alarm tags have been read successfully.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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6 Show Historical Data Chart Phase (SR0110+)

The **Show historical data chart** phase allows to show a time series chart for historical data.

Example use cases are:

- History of a full process run
  Display an overview of a full process run with various process parameters. This can be used as a trigger for further analysis with other tools if required.

- History of a specific timeframe
  Display a detailed process view of a specific timeframe with one or more process parameters to see if unexpected or irregular values have occurred.

The phase supports FactoryTalk Historian.

TIP

Chart rendering will fail if negative values are to be rendered on a logarithmic scale.

Values are only rendered in the chart when they exist at the specific point of time and lie within the configured period and y-axis values of the plot.

The affected equipment entity, the query template, and the time series chart are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2669668).

Anomalies that occur during processing are covered by the phase exception handling (GID-2669668)(e.g. no chart available).

After completion the phase displays the affected equipment entity and the time series chart in the Execution Window.

The Navigator displays the identifier of the affected equipment entity.
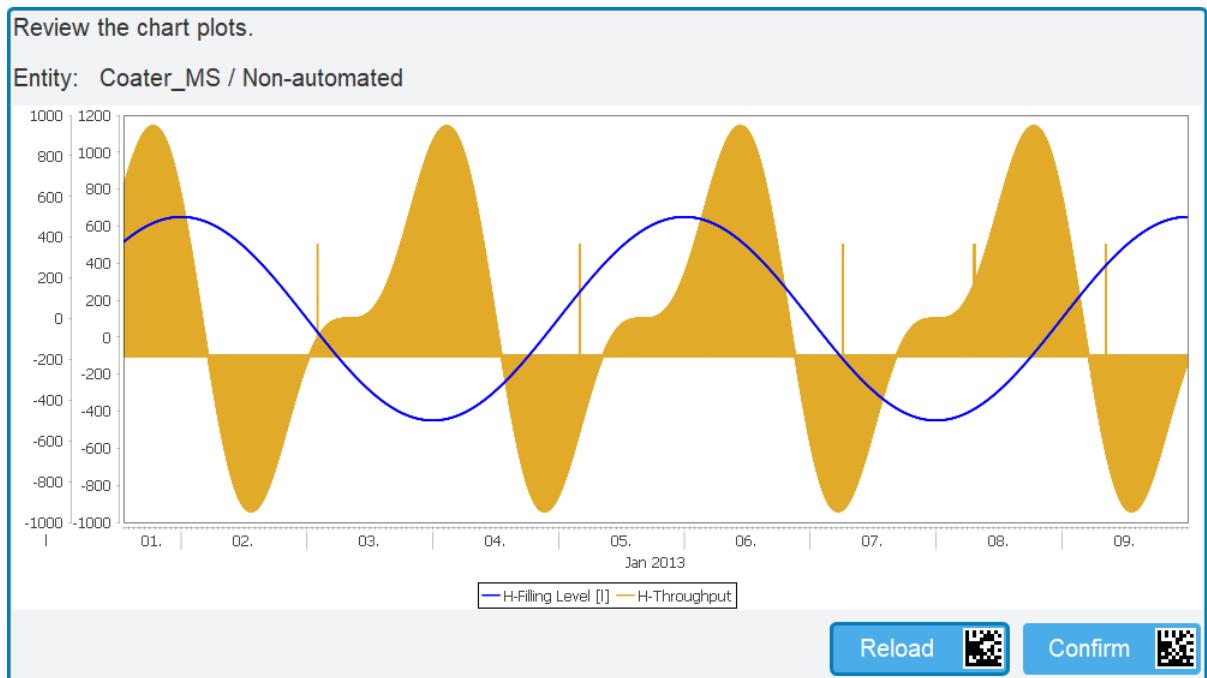
Figure 5: Show historical data chart during execution

6.1 Layout

The phase provides individual layouts for its representation during execution (GID-2669666), in the Navigator (GID-2669667), and in the sub-report (GID-2669668)

6.1.1 Representation during Execution (SR0110.1+)

The representation during execution depends on the phase mode.

6.1.1.1 GID-2671382 PREVIEW MODE (SR0110.1.1)

1. <Instruction text>
   (taken from **Instruction (SR0110.8.1)** process parameter (GID-2671394))

2. Entity:

3. **Reload** button (disabled).

4. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

6.1.1.2 GID-2671383 ACTIVE MODE (SR0110.1.2)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0110.8.1)** process parameter (GID-2671394))

3. Entity: <equipment entity identifier>
   (taken from **Identified equipment entity (SR0110.8.2)** process parameter (GID-2671395))

4. Time series chart
   (configuration taken from **Chart plot (SR0110.8.3)** process parameter (GID-2671396)and **Chart axis (SR0110.8.4)** process parameter (GID-2671398)

5. **Reload** button.

6. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.1.1.3 GID-2671384 COMPLETED MODE (SR0110.1.3)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0110.8.1)** process parameter (GID-2671394))

3. Entity: <equipment entity identifier>
   (taken from **Identified equipment entity (SR0110.8.2)** process parameter (GID-2671395))

4. Time series chart
   (configuration taken from **Chart plot (SR0110.8.3)** process parameter (GID-2671396)and **Chart axis (SR0110.8.4)** process parameter (GID-2671398))

5. **Reload** button (disabled).

6. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.1.2 Representation in Navigator (SR0110.4+)

The Navigator provides the following details:

6.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>

    - Example:
      Review Data Chart

6.1.2.2 GID-2671386 INFORMATION COLUMN (SR0110.4.1)

- <Identifier of affected equipment entity>

    - Example: Coater_S

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

6.1.2.3 ACTION COLUMN

- There are no actions available.

6.1.3 Representation in Sub-report (SR0110.5+)

The sub-report contains the following information:

6.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>

- <Completion time>

- <Unit procedure> / <operation> / <phase>

- <Work center> / <station> / <device> - <phase completion user>

6.1.3.2 GID-2671389 SUB-REPORT ELEMENTS (SR0110.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)

- Time series chart

- Instruction text

- Entity (identifier)

- Queries

    - Property (identifier)

    - Query template (identifier)

    - Executed query (symbolic notation with input values represented as string; not necessarily
      directly executable due to potentially required data type conversion functions when executed
      on SQL layer)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.2 Business Logic (SR0110.2+)

The phase implements the following business logic.

6.2.1 GID-2669669 Display chart (SR0110.2.1)

- Function: Display a chart with values from the Historian system

- Trigger: Phase becomes active

- Postcondition: Chart is displayed

Step	#	Description
Check configuration	10	Phase displays its user interface according to the **Active mode (SR0110.1.2)** layout (GID-2671383)with the chart image placeholder and the embedded text **No chart generated**. Phase evaluates the configuration of the **Identified equipment entity (SR0110.8.2)** process parameter (GID-2671395), **Chart plot (SR0110.8.3)** process parameter (GID-2671396), and **Chart axis (SR0110.8.4)** process parameter (GID-2671398)for consistency. If one of the following issues occurs, phase displays the **Invalid configuration error (SR0110.3.6.1)** error message (GID-2669681): - Identified equipment entity is not defined. - Configured chart plot property is not defined for the entity. - No Y-axis with a corresponding unit of measure is defined for chart plot property. - There are more properties with different units of measure than corresponding y-axes. - There are several Y-axes defined with the same unit of measure (duplicate). - No query template has been selected for an enabled chart plot. - No property has been selected for an enabled chart plot. - No plot format has been selected for an enabled chart plot. - No Y-axes range values have been defined if **Autorange** is disabled for an enabled chart axis.

Step	#	Description
Data retrieval	20	Phase retrieves data from the Historian system based on the parameterized query template. Phase displays chart image placeholder with loading data indicator while retrieving data. If the data cannot be loaded, phase displays the **Data retrieval error (SR0110.3.6.2)** error message (GID-2669682).
Display chart	30	▪ If data retrieval was successful, phase saves the generated chart image and displays it. ▪ Chart will be displayed using the horizontal size of the PEC work area. ▪ Otherwise, phase displays chart image placeholder with the embedded text **No chart generated**.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.2.2 GID-2669670 Reload chart (SR0110.2.2)

▪ Function: Execute data retrieval and update the displayed chart

▪ Trigger: Operator reloads chart data

▪ Postcondition: Reloaded chart is displayed

Step	#	Description
Check configuration	10	Phase evaluates the configuration of the **Identified equipment entity (SR0110.8.2)** process parameter (GID-2671395), **Chart plot (SR0110.8.3)** process parameter (GID-2671396), and **Chart axis (SR0110.8.4)** process parameter (GID-2671398)) for consistency. If one of the following issues occurs, phase displays the **Invalid configuration error (SR0110.3.6.1)** error message (GID-2669681) ▪ Identified equipment entity is not defined. ▪ Configured chart plot property is not defined for the entity. ▪ No Y-axis with a corresponding unit of measure is defined for chart plot property. ▪ There are more properties with different units of measure than corresponding y-axes. ▪ There are several Y-axes defined with the same unit of measure (duplicate).

Step	#	Description
		▪ No query template has been selected for an enabled chart plot. ▪ No property has been selected for an enabled chart plot. ▪ No plot format has been selected for an enabled chart plot. ▪ No Y-axes range values have been defined if **Autorange** is disabled for an enabled chart axis.
Data retrieval	20	Phase retrieves data from the Historian system based on the parameterized query template. Phase displays chart image placeholder with loading data indicator while retrieving data. If the data cannot be loaded, phase displays the **Data retrieval error (SR0110.3.6.2)** error message (GID-2669682).
Display chart	30	▪ If data retrieval was successful, phase saves the generated chart image and displays it. ▪ Chart will be displayed using the horizontal size of the PEC work area. ▪ Otherwise, phase displays chart image placeholder with the embedded text **No chart generated**.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.2.3 GID-2669671 Confirm phase (SR0110.2.3)

▪ Function: Completion of phase

▪ Trigger: Operator confirms phase

▪ Postcondition: Phase is completed

Step	#	Description
Operator confirms phase	10	▪ If no chart is displayed and the **Chart unavailable (SR0110.3.1.1)** user-triggered exception (GID-2669682)has not been signed, phase displays **Chart unavailable error (SR0110.3.6.2)** error message (GID-2669682). In this case, the **Chart unavailable (SR0110.3.1.1)** user-triggered exception (GID-2671400)needs to be recorded before the phase can be completed. ▪ Otherwise, phase is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.2.4 GID-2669672 Resume phase (SR0110.2.4)

- Function: Resuming of phase
  The phase was in the **Active mode (SR0110.1.2)** status (GID-2671383)when the Production Execution Client was shut down.

- Trigger: At restart of the Production Execution Client, phase is resumed.

- Postcondition: Phase is active

Step	#	Description
System resumes phase	10	Phase displays the chart image placeholder with the embedded text **No chart generated.**
Display saved chart	20	If the chart has been generated and stored before, phase loads and displays the saved chart image.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.2.5 GID-3522600 Resize PEC

- Function: Resizing of PEC.

- Trigger: Operator resizes PEC work area.

- Postcondition: No change in chart display.

Step	#	Description
Operator resizes PEC	10	Chart is not resized.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.3 Process Parameters (SR0110.8+)

The following process parameters define the behavior of the phase.

6.3.1 Instruction Table-specific Parameters

6.3.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

6.3.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. **Restriction**: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

6.3.2 Instruction Link-specific Parameters

6.3.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Instruction text	HTML text	Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2671393). Example: Refer to {SOP1270} for guidance. Maximum length is 2000 characters (including HTML tags).

6.3.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

6.3.3 Basic Parameters

6.3.3.1 GID-2671394 INSTRUCTION (SR0110.8.1)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed. **Restriction**: Maximum length is 4000 characters (including HTML tags).
Column 2	HTML text	Not used.
Column 3	HTML text	

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.3.3.2 GID-2671395 IDENTIFIED EQUIPMENT ENTITY (SR0110.8.2)

Attribute	Type	Comment
Equipment object	Reference	Reference to the output of a preceding phase that provides an identified equipment entity.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.3.4 Chart Parameters

6.3.4.1 GID-2671396 CHART PLOT (SR0110.8.3)

The attributes are available for each of the 16 **Chart plot** process parameters (Plot 1 - Plot 16).

Attribute	Type	Comment
Enabled	Flag	Controls if the plot configuration is used to draw a plot.
Property	String	Historian point to be read.

Attribute	Type	Comment
Query template	Choice list	Defines the template to be used for data retrieval. By default, the system provides three templates: **Raw archive data** provides all archived data for the history period. **Plot data** provides the data dedicated to plotting (trending) applications within the history period. **Marker (DigitalState)** provides the string values within the history period that are available for use as segment markers.
Plot format	Choice list	Defines the plot drawing to be used with regard to line color, thickness, and line pattern.
Timestamp 1	Timestamp	Optional parameter to be passed to the query template for query-specific usage. Evaluated as data retrieval start date and time for system-defined query templates (**Raw archive data**, **Plot data**, **Marker (DigitalState)**).
Timestamp 2	Timestamp	Optional parameter to be passed to the query template for query-specific usage. Evaluated as data retrieval end date and time for system-defined query templates (**Raw archive data**, **Plot data**, **Marker (DigitalState)**).
String 1	String	Optional parameter to be passed to the query template for query-specific usage.
String 2	String	Optional parameter to be passed to the query template for query-specific usage.

Attribute	Type	Comment
Duration	Duration	Optional parameter to be passed to the query template for query-specific usage.
Long	Long	Optional parameter to be passed to the query template for query-specific usage.
MeasuredValue 1	MeasuredValue	Optional parameter to be passed to the query template for query-specific usage.
MeasuredValue 2	MeasuredValue	Optional parameter to be passed to the query template for query-specific usage.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.3.4.2 PROPERTY SELECTION EDITOR (FRAMEWORK CAPABILITY)

The system provides a Property Selection editor for selecting an equipment property based on its data type (numeric, string, boolean). The supported data types depend on the process parameter.

6.3.4.3 GID-2671398 CHART AXIS (SR0110.8.4)

The attributes are available for each of the 4 **Chart axis** process parameters (Axis 1 - Axis 4).

Attribute	Type	Comment
Enabled	Flag	Controls if the axis configuration is used to draw an axis.
Unit of measure	Choice list	Defines the unit of measure for the axis and thus its label.
Minimum	Numeric	The minimum value shown on the y-axis. A value is required if **Autorange** is disabled.

Attribute	Type	Comment
Maximum	Numeric	The maximum value shown on the y-axis. A value is required if **Autorange** is disabled.
Autorange	Flag	Defines if the minimum and maximum values of the y-axis are to be determined automatically. If so, the values defined for the **Minimum** and **Maximum** attributes are ignored. Default setting: **Yes**
Scaling mode	Choice list	Defines the scaling mode. Available settings: **Linear**, **Logarithmic**. Default setting: **Linear**.
Number format	String	Defines the format pattern for numeric values. Examples: **0**: Integer portion of a number. **0.0**: Integer portion and one fractional digit. **0.00**: Integer portion and two fractional digits. Default setting: **0**.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.3.5 Configuration of User-triggered Exceptions

6.3.5.1 GID-2671399 CHART UNAVAILABLE (SR0110.8.5)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).** Default setting: **High.**
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 256 characters.

See also **Chart unavailable (SR0110.3.1.1)** user-triggered exception (GID-2671400).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.4 Exceptions (SR0110.3+)

The phase supports user-defined, user-triggered (GID-2669679), system-triggered (GID-2669678), and post-completion exceptions (GID-2669680)and their configuration by means of process parameters (GID-2668258).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

6.4.1 System-triggered Exceptions

There are no system-triggered exceptions available.

6.4.2 User-triggered Exceptions (SR0110.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

6.4.2.1 GID-2671400 CHART UNAVAILABLE (SR0110.3.1.1)

The **Chart unavailable** exception allows an operator to confirm the phase without a chart.

Representation during exception handling:

- Instruction:
  Confirm without chart.
  Confirm button.

- Exception text:
  <Exception text>
  (taken from **Chart unavailable (SR0110.8.5)** process parameter (GID-2671399))

  - Example:
    Confirmed without chart.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.4.2.2 GID-2671401 CHART UNAVAILABLE - LOGIC (SR0110.3.1.1.1)

- Trigger: Exception is selected

- Postcondition: Phase can be confirmed

Step	#	Description
Operator confirms exception	10	Phase shows exception description to be signed according to **Chart unavailable (SR0110.8.5)** process parameter (GID-2671399).
Operator signs exception	20	Phase records the exception.
Phase activation	30	Phase returns to the **Active mode (SR0110.1.2)** layout (GID-2671383)and disables the **Reload** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

6.5 Information Messages

There are no information messages available.

6.6 Questions

There are no questions available.

6.7 Decisions

There are no decisions available.

6.8 Error Messages (SR0110.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

6.8.1 GID-2669681 Invalid configuration error (SR0110.3.6.1)

UI text	Comment
One or more configuration errors have occurred:	Message pack: PhaseShwHstDatChrt<version> Message ID: InvalidConfigurationError_Category
Entity not defined.	Message pack: PhaseShwHstDatChrt<version> Message ID: EntityUndefined_ErrorMsg
<entity identifier> entity has no <property identifier> property. (<parameter ID>) … <entity identifier> entity has no <property identifier> property. (<parameter ID>)	Message pack: PhaseShwHstDatChrt<version> Message ID: EntityHasNoProperty_ErrorMsg
No Y-axis for <UoM> defined for <property identifier> property. (<parameter ID>) … No Y-axis for <UoM> defined for <property identifier> property. (<parameter ID>)	Message pack: PhaseShwHstDatChrt<version> Message ID: UOMUndefinedForYAxis_ErrorMsg

UI text	Comment
No Y-axis without unit of measure defined for <property identifier> property. (<parameter ID>) ... No Y-axis without unit of measure defined for <property identifier> property. (<parameter ID>)	Message pack: PhaseShwHstDatChrt<version> Message ID: NoUOMUndefinedForYAxis_ErrorMsg
Too many different units of measure defined to be displayed on available Y-axes.	Message pack: PhaseShwHstDatChrt<version> Message ID: TooManyUOMsDefined_ErrorMsg
A unit of measure has been defined more than once for the Y-axes.	Message pack: PhaseShwHstDatChrt<version> Message ID: DuplicatedUOMForYAxis_ErrorMsg
Query template not defined. (<parameter ID>, ...)	Message pack: PhaseShwHstDatChrt<version> Message ID: UndefinedQueryTemplate_ErrorMsg
Property not defined. (<parameter ID>, ...)	Message pack: PhaseShwHstDatChrt<version> Message ID: UndefinedPropertyType_ErrorMsg
Plot format not defined. (<parameter ID>, ...)	Message pack: PhaseShwHstDatChrt<version> Message ID: UndefinedPlotFormat_ErrorMsg
Range not defined. (<parameter ID>, ...)	Message pack: PhaseShwHstDatChrt<version> Message ID: UndefinedRange_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.8.2 GID-2669682 Data retrieval error (SR0110.3.6.2)

UI text	Comment
Cannot retrieve the requested data. Please contact your system administrator.	Message pack: PhaseShwHstDatChrt<version> Message ID: ChartGeneration_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.8.3 GID-2669683 Chart unavailable error (SR0110.3.6.3)

UI text	Comment
Cannot complete the phase, since there is no chart available.	Message pack: PhaseShwHstDatChrt<version> Message ID: ChartUnavailable_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.9 Output Variables (SR0110.9+)

The following output variables are available to reference the phase's output.

6.9.1 Instance count (Framework capability)

- Data type: Long

- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

6.9.1.1 START TIME (FRAMEWORK CAPABILITY)

- Data type: Timestamp

- Usage: The output variable provides the start time of the phase.

6.9.1.2 COMPLETION TIME (FRAMEWORK CAPABILITY)

- Data type: Timestamp

- Usage: The output variable provides the completion time of the phase.

6.9.1.3 IDENTIFIER (FRAMEWORK CAPABILITY)

- Data type: String

- Usage: The output variable provides the identifier of the phase.

6.9.1.4 GID-2671405 CHART AVAILABLE (SR0110.9.1)

- Data type: Boolean

- Usage: The output variable states if the chart is available (TRUE) or not (FALSE).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.10 Configuration Keys (SR0110.11+)

The following configuration keys are available to configure the phase's behavior.

6.10.1 GID-2669685 Chart resolution (SR0110.11.1)

- Phase/ShowHistoricalDataChartPhase/HistoricalDataChartReportResolution

- **Type**: String

- **Value**: 300

- **Description**: Defines the chart resolution in DPI for batch report printout.

- **Range**: N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.10.2 GID-2669686 Anti-aliasing for plots (SR0110.11.4)

- Phase/ShowHistoricalDataChartPhase/HistoricalDataChartsetPlotAntiAlias

- **Type**: Boolean

- **Value**: True

- **Description**: If the value is set to **true**, anti-aliasing is enabled for plots.

- **Range**: N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.10.3 GID-2669687 Anti-aliasing for text (SR0110.11.5)

- Phase/ShowHistoricalDataChartPhase/HistoricalDataChartsetTextAntiAlias

- **Type**: Boolean

- **Value**: False

- **Description**: If the value is set to **true**, anti-aliasing is enabled for text.

- **Range**: N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.10.4 GID-2669688 Plot renderers (SR0110.11.2)

- **Phase/ShowHistoricalDataChartPhase/PlotRenderers**

- **Type**: Object - List

- **Value**:

```xml
<?xml version="1.0" encoding="UTF-8"?>
<plotRenderers xmlns="http://www.rockwell.com/mes/commons/base/graph">
<plotRenderer name="Black" description="Black solid 1.5pt">
<paint red="0" green="0" blue="0"/>
<stroke/>
</plotRenderer>
<plotRenderer name="Red" description="Red solid 1.5pt">
<paint red="255" green="0" blue="0"/>
<stroke/>
</plotRenderer>
<plotRenderer name="Green" description="Greed solid 1.5pt">
<paint red="32" green="172" blue="32"/>
<stroke/>
</plotRenderer>
<plotRenderer name="Blue" description="Blue solid 1.5pt">
<paint red="0" green="0" blue="255"/>
<stroke/>
</plotRenderer>
<plotRenderer name="Magenta" description="Magenta solid 1.5pt">
<paint red="255" green="0" blue="255"/>
<stroke/>
</plotRenderer>
<plotRenderer name="Cyan" description="Cyan solid 1.5pt">
<paint red="0" green="223" blue="218"/>
<stroke/>
</plotRenderer>
<plotRenderer name="Orange" description="Orange solid 1.5pt">
<paint red="225" green="170" blue="40"/>
<stroke/>
</plotRenderer>
<plotRenderer name="Light green" description="Light green solid 1.5pt">
<paint red="0" green="226" blue="0"/>
<stroke/>
</plotRenderer>
<plotRenderer name="Light blue" description="Light blue solid 1.5pt">
<paint red="33" green="160" blue="223"/>
```

```
<stroke/>
</plotRenderer>
<plotRenderer name="Purple" description="Purple solid 1.5pt">
<paint red="161" green="67" blue="255"/>
<stroke/>
</plotRenderer>
<plotRenderer name="Light red" description="Light red solid 1.5pt">
<paint red="255" green="125" blue="125"/>
<stroke/>
</plotRenderer>
<plotRenderer name="Petrol" description="Petrol solid 1.5pt">
<paint red="18" green="157" blue="140"/>
<stroke/>
</plotRenderer>
<plotRenderer name="Brown" description="Brown solid 1.5pt">
<paint red="124" green="90" blue="76"/>
<stroke/>
</plotRenderer>
<plotRenderer name="Tan" description="Tan solid 1.5pt">
<paint red="179" green="175" blue="13"/>
<stroke/>
</plotRenderer>
<plotRenderer name="Livid" description="Livid solid 1.5pt">
<paint red="113" green="135" blue="199"/>
<stroke/>
</plotRenderer>
<plotRenderer name="Dark red" description="Dark red solid 1.5pt">
<paint red="192" green="80" blue="77"/>
<stroke/>
</plotRenderer>
<plotRenderer name="Tan dash dot" description="Tan dash-dotted 1.5pt">
<paint red="179" green="175" blue="13"/>
<stroke lineJoin="1" miterLimit="3.0">
<dashArray>6.0</dashArray>
<dashArray>3.0</dashArray>
<dashArray>1.0</dashArray>
<dashArray>3.0</dashArray>
</stroke>
</plotRenderer>
<plotRenderer name="Black dashed" description="Black dashed 1.5">
<paint red="0" green="0" blue="0"/>
<stroke>
<dashArray>6.0</dashArray>
<dashArray>3.0</dashArray>
</stroke>
</plotRenderer>
</plotRenderers>
```

- **Description**: Specifies the list of plot renderers available for the plot-related process parameters of the **Show historical data chart** phase.

  For more information, please refer to section "Configuring Plot Styles for Historical Data Charts", chapter "Administration" in the "Technical Guide Phases of the Equipment Automation Package" [A4] (GID-2667986).

- **Range**: N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.10.5 GID-2669689 Query templates (SR0110.11.3)

- **Phase/ShowHistoricalDataChartPhase/QueryTemplates**

- **Type**: Object - List

- **Value**:

```
<QueryTemplates xmlns="http://www.rockwell.com/mes/commons/base/query">
<QueryTemplate name="Raw archive data" description="All raw archive values within
defined
period." usage="chart">
<Parameters>
<Parameter name="Property" description="pi-point" datatype="String"
systemdefined="true"/>
<Parameter name="Timestamp1" description="start-time" datatype="DateTime"/>
<Parameter name="Timestamp2" description="end-time" datatype="DateTime"/>
</Parameters>
<Outputs>
<Parameter name="value" description="numeric tag value" datatype="Float"
systemdefined="true"/>
<Parameter name="time" description="time stamp" datatype="DateTime"
systemdefined="true"/>
</Outputs>
<Query provider="OSI_PI">SELECT if status = 0 THEN value ELSE null "value", time
FROM
piarchive..picomp WHERE tag=%Property% AND time BETWEEN %Timestamp1% AND
%Timestamp2%</Query>
</QueryTemplate>
<QueryTemplate name="Plot data" description="Data dedicated to plotting (trending)
applications within defined period." usage="chart">
<Parameters>
<Parameter name="Property" description="pi-point" datatype="String"
systemdefined="true"/>
<Parameter name="Timestamp1" description="start-time" datatype="DateTime"/>
<Parameter name="Timestamp2" description="end-time" datatype="DateTime"/>
<Parameter name="intervalCount" description="#ofPixels" datatype="Long"
systemdefined="true"/>
</Parameters>
<Outputs>
<Parameter name="value" description="numeric tag value" datatype="Float"
systemdefined="true"/>
<Parameter name="time" description="time stamp" datatype="DateTime"
systemdefined="true"/>
</Outputs>
<Query provider="OSI_PI">SELECT if status = 0 THEN value ELSE null "value", time
FROM
piarchive..piplot WHERE tag=%Property% AND time BETWEEN %Timestamp1% AND
%Timestamp2% AND intervalCount = %intervalCount%</Query>
</QueryTemplate>
<QueryTemplate name="Marker (DigitalState)" description="All digital state string
values
for chart within defined period used as segment markers." usage="chart">
<Parameters>
<Parameter name="Property" description="pi-point" datatype="String"
systemdefined="true"/>
<Parameter name="Timestamp1" description="start-time" datatype="DateTime"/>
```

```
<Parameter name="Timestamp2" description="end-time" datatype="DateTime"/>
</Parameters>
<Outputs>
<Parameter name="value" description="string tag value" datatype="String"
systemdefined="true"/>
<Parameter name="time" description="time stamp" datatype="DateTime"
systemdefined="true"/>
</Outputs>
<Query provider="OSI_PI">SELECT DIGSTRING(status) "value", time FROM
piarchive..picomp
WHERE tag=%Property% AND time BETWEEN %Timestamp1% AND %Timestamp2%</Query>
</QueryTemplate>
</QueryTemplates>
```

- **Description**: Specifies the list of query templates available for the plot-related process parameters of the **Show historical data chart** phase.

  For more information, please refer to section "Configuring Query Templates for Historical Data Charts", chapter "Administration" in the "Technical Guide Phases of the Equipment Automation Package" [A4] (GID-2667986).

- **Range**: N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.10.6 GID-2669690 Provide shortcuts (SR0110.11.6)

- Phase/ShowHistoricalDataChartPhase/ProviderShortcuts

- **Type**: List

- **Value**: (PiConnector=OSI_PI, PiMockConnector=CSV_MOCK)

- **Description**: Defines shortcuts for providers. The shortcuts can be used within QueryTemplateXML, e.g. <Query provider="OSI_PI">.

  Each entry must be formatted as follows: key=value, e.g. PiConnector=OSI_PI

- **Range**: N/A

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.11 Performance (SR0110.12+)

Reference scenario

The reference scenario holds a total of:

▪ 16 Historian properties

Data volume perspective:

▪ properties with less than 100 data points retrieved

▪ properties with more than 2,000 data points retrieved

▪ 3 properties with more than 4,000 data points retrieved

▪ 4 properties with more than 20,000 data points retrieved

Query template perspective:

▪ 8 properties using the **Raw archive data** query template

▪ 6 properties using the **Plot data** query template

▪ 2 properties using the **Marker (DigitalState)** query template

▪ 3 different query templates for data retrieval (**Raw archive data**, **Plot data**, **Marker (DigitalState)**)

Example for **Raw archive data** query template:

▪ SELECT if status = 0 THEN value ELSE null "value", time FROM piarchive..picomp WHERE tag=%Property% AND time BETWEEN %Timestamp1% AND %Timestamp2%Each: 3 subsequent operations

▪ 14 days as duration for data retrieval

The setup of the Historian Infrastructure for PharmaSuite is performed using the normal access topology as defined in Automation Integration Configuration Scenarios (see "Technical Guide Installation" [A3] (GID-2667986)).

6.11.1 GID-2669691 Performance of Chart Rendering (SR0110.12.1)

Based on the Reference scenario (GID-2668266), the rendering of a trend chart does not take longer than 10 seconds in the PharmaSuite system test environment. The duration is measured between activation of the phase and displaying the chart image.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

7 Reference Documents

The following documents are available from the Rockwell Automation Download Site.

No.	Document Title	Part Number
A1	FT PharmaSuite Functional Requirement Specification Execution Framework	PSFRSEF-RM007B-EN-E
A2	FT PharmaSuite Functional Requirement Specification Recipe and Workflow Management	PSFRSRD-RM011B-EN-E
A3	FT PharmaSuite Technical Guide Installation	PSES-IN011B-EN-E
A4	FT PharmaSuite Technical Guide Phases of the Equipment Automation Package	PSEA-PM005A-EN-E

TIP

To access the Rockwell Automation Download Site, you need to acquire a user account from Rockwell Automation Sales or Support.

8 Document Information

The document information covers various data related to the document.

8.1 Approval

This document has been approved electronically via the Rockwell Automation Document Management System (DMS). The required approvers of this document include the following:

Name	Role
Norbert Ern	Product Owner
Fabian Hofsäß	Technical Lead
Ignaz Wangler	Test Lead

8.2 Version Information

Object	Version
FT PharmaSuite	11.01.00
Get OPC Values	11.1
Set OPC Values	11.1
Monitor Numeric Value	11.0
Get Alarms	11.0
Show Historical Data Chart	11.1
Functional Requirement Specification	1.0

9 Appendix A - Revision History

9.1 Updated Requirements

GID-2667981 Get OPC Values Phase (SR0341+)

GID-2671220 Sub-report elements (SR0341.5.1)

GID-2671229 Instruction (SR0341.8.1)

GID-2671237 Expected value definition (SR0341.8.14)

GID-2671249 Limit violation (SR0341.3.2.1)

GID-2671802 Override recorded value (SR0341.3.1.3)

GID-2671804 Override recorded value (SR0341.3.1.1)

GID-2671806 Override recorded value (SR0341.3.1.2)

GID-2669431 Override value recorded (SR0341.3.4.1)

GID-2667982 Set OPC Values Phase (SR0342+)

GID-2671276 Completed mode (SR0342.1.3)

GID-2671285 Confirm phase (SR0342.2.4)

GID-2671290 Instruction (SR0342.8.1)

GID-2671293 Override value definition (SR0342.8.4)

GID-2671294 Input at equipment (SR0342.8.5)

GID-2671809 Override value definition (SR0342.3.1.4)

GID-2671811 Override value definition (SR0342.3.1.2)

GID-2671813 Override value definition (SR0342.3.1.3)

GID-2671310 Input at equipment recorded (SR0342.3.6.2)

GID-2671314 Error message grouping (SR0342.3.6.6)

GID-2671315 Defined values not set (SR0342.3.6.7)

GID-2671316 Error message grouping - Confirm (SR0342.3.6.8)

GID-2671346 Instruction (SR0360.8.1)

GID-2671371 Instruction (SR0365.8.1)

GID-2667985 Show Historical Data Chart Phase (SR0110+)

GID-2669669 Display chart (SR0110.2.1)

GID-2669670 Reload chart (SR0110.2.2)

GID-2671394 Instruction (SR0110.8.1)

GID-2671399 Chart unavailable (SR0110.8.5)

GID-2669688 Plot renderers (SR0110.11.2)

GID-2669689 Query templates (SR0110.11.3)

GID-2669690 Provide shortcuts (SR0110.11.6)

GID-2668266 Performance (SR0110.12+)

GID-2669691 Performance of Chart Rendering (SR0110.12.1)

9.2 Added Requirements

GID-3522600 Resize PEC

9.3 Deleted Requirements

None

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